



National Bioethics Committee



Guidelines and Teachers Handbook for Introducing Bioethics to Medical and Dental Students

**Developed by:
Healthcare Ethics Committee (HCEC)
of the
National Bioethics Committee (NBC)**

<http://nbcPakistan.org.pk/>

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Foreword

April 29, 2017

The primary responsibility of the Health Care Ethics Committee (HCEC) of the National Bioethics Committee (NBC) Pakistan, is to develop and utilize strategies to enhance bioethics capacity in Pakistan. To accomplish this, HCEC organizes and runs bioethics workshops for professionals involved in biomedical research and healthcare delivery systems and members of Regional and Provincial Bioethics Committees. Recognizing that HCEC should also assist in ways to introduce bioethics to undergraduate medical and dental students and little progress has been made in this equally important area, led to the development of this document.

In its first Code of Ethics for healthcare professionals, formulated in 2002, the Pakistan Medical and Dental Council (PMDC) stated that medical and dental colleges, College of Physicians and Surgeons, and universities running postgraduate medical courses “are advised to incorporate medical ethics in their curriculum.” In reality, currently only a handful of medical and dental colleges include any bioethics education as part of their curriculum for students. It is within this background, to address this deficiency, that HCEC worked to develop this comprehensive document, “**Guidelines and Teachers Handbook for Introducing Bioethics to Medical and Dental Students.**” It is meant to assist universities and colleges in developing their own bioethics curriculum and it also provides useful tools for teachers involved in teaching this discipline. All articles/chapters included in this document are either from the Creative Commons (non-copyright material), or with permission obtained from relevant publishers for full reproduction. Sources are linked for easy accessibility. As and when necessary, HCEC will review and update this document in the future.

The process of developing this document extended from February 2013 to August 2014. It included multiple meetings of HCEC, and presentation and discussion of drafts with NBC members for their input. NBC provided its final approval in March 2015. Bringing this document to fruition would not have been possible without the unstinting hard work and long hours spent by HCEC members and other professionals with relevant expertise who were co-opted for this process. A list of these colleagues and their backgrounds, and to whom I remain immensely grateful, appears on the next page.

On April 25, 2017, the complete document was presented and discussed in a special meeting in Islamabad called by Mr. Muhammad Ayub Sheikh, Secretary, Ministry of National Health Services, Regulations and Coordination. Besides HCEC members and the Secretary, other relevant participants in the meeting included representatives from PMDC, HEC, and CPSP. The document was appreciated for its relevance and importance, and PMDC was asked to endorse and notify it as a resource document for all medical and dental colleges in Pakistan. The PMDC representative, Dr. Abid Farooqui (Vice President PMDC), promised that this will be done.

We appreciate the help of Dr. Waquaruddin Ahmad and Mr. Roshan Kumar from Pakistan Health Research Council (PHRC), Sindh, Pakistan. Our thanks especially to the staff of the Centre of Biomedical Ethics and Culture (CBEC), SIUT - Michelle Fernandes, Aamir Shehzad and Loretta Iqbal - for their time and meticulous help in formulating the document in its final form.

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Introduction

The Pakistan Medical and Dental Council (PMDC) formulated its first Code of Ethics in 2002 which stipulated that biomedical ethics should be taught in all medical/dental colleges in the country. This Code was updated in June 2011 and reissued as the “Code of Ethics of Practice for Medical and Dental Practitioners, Regulations 2011”.¹ [\(PMDC Code of Ethics\)](#) The Code advises that medical ethics should be incorporated in the curriculum of all medical and dental colleges, the College of Physicians and Surgeons of Pakistan as well as by Universities running postgraduate medical courses, and calls for “strategies” for the dissemination of information about ethics. Despite this, no formal steps have been taken in this direction, nor is guidance available at a national level for institutions who may wish to undertake teaching of bioethics. Only a handful of colleges and universities in the private and public sector currently include sessions on ethics to varying degrees as part of their undergraduate medical and dental teachings.

The concept of professional codes of conduct for healthcare professionals is not a new phenomenon and can be traced back to the era of Hammurabi (3000 BCE). A better known text is the Hippocratic Oath (500 BCE) which still forms the basis for many oaths taken by students upon graduation from medical colleges today. Examples of professional codes are also found in major religious traditions such as Al-Ruhawi’s *Adab at Tabib* (900 BCE) in Islam and by Moses Maimonides (1200 BCE) in Judaism. These earlier codes, written exclusively by physicians for physicians, focused on the character and duties of professionals and emphasized the principle of beneficence in which the physician decides what lies in the best interest of the patient. These traditional codes, still important today in their emphasis on the virtues required for a good healthcare professional, were formulated during times when medical knowledge was relatively limited and physicians had little to offer in the way of diagnosis and therapy to their patients.

The twentieth century saw an explosion in the advancement of medical science, biotechnology, and complex human subject research which changed the face of medical practice and research giving rise to novel ethical dilemmas. Examples included the advent of ventilators allowing irrevocably comatose patients to be kept “alive” for weeks, the capability of transplanting organs from one individual to another, and breakthroughs in genetic and reproductive science. Together with this, the nature of medical practice changed from a relationship between a healthcare giver and his/her patient to a health industry consisting of depersonalized hospitals often run on profit basis and several specialists involved in the care of one patient. Modern medicine led to complex ethical dilemmas that required new solutions, and for which traditional codes alone became inadequate.

Contemporary (modern) bioethics emerged in the USA in the 1960s in response to the changing nature of physician-patient interactions, healthcare delivery systems, and the increasing complexity of human subject research. It was driven by several scandalous cases in which patients and research subjects had been exploited by physicians and researchers withholding or providing inadequate information to them. The defining characteristic of bioethics involved a shift from exclusive reliance on medical “facts,” and knowledge and authority of physicians (doctor centered) to recognition that patients have intrinsic rights as equal partners in decisions about therapy and what constitutes their best interest (patient centered). The requirement for providing full information and voluntary consent of subjects also became the key element for ethical research.

¹ PMDC Code of Ethics:
<http://www.pmdc.org.pk/LinkClick.aspx?fileticket=v5WmQYMvzh4%3D&tabid=102&mid=554>.

Unlike the exclusively physician generated traditional codes of ethics, bioethics is a multidisciplinary field. It incorporates input from non-medical sciences such as philosophy (rational, logical argumentation tools), comparative theology and religious positions (less so in “secular” societies), law (which informs and is informed by ethics), sociology (highlighting importance of cultural contexts and diversity of human norms of right and wrong), and humanities (literary traditions that reflect the moral sense of societies). An important feature of bioethics is to inculcate critical thinking and the ability to analyze and resolve situations in which values of protagonists – patients, their families, and healthcare professionals – come in conflict while keeping respect for patients and research subjects paramount.

Need for Bioethics Education in Pakistan

In Pakistan, as is the case in many other developing countries, healthcare professionals and hospitals, in public and private domains, now offer almost all forms of tertiary medical care services. There is also increasing national and institutional pressure for conducting biomedical research which attracts international funding while helping individuals to advance in academia. All this is occurring in the absence of sufficient knowledge and systematic attention to the many ethical issues raised by both modern medicine and research, and which are compounded by weak or absent accountability systems in place against unethical practices. Despite the popular rituals of including talks on ethics in local conferences and seminars there appears to be little impact in reducing unethical clinical practices judging by reports that surface regularly. This reality is amply demonstrated today in the way we practice medicine, conduct research, and the lack of meaningful ethics education to students and healthcare professionals in Pakistan.² ([Pakistan and Biomedical Ethics](#))

As the practice of medicine assumes the garb of a business industry in Pakistan, medical and dental colleges may be turning out practitioners with appropriate technical knowledge and expertise yet graduates by and large lack even basic understanding of ethics. They do not possess necessary professional qualities to help them meet the challenges of the increasingly complex practice of medicine and daily encounters with unethical practices. Similarly, with the progressive outsourcing of biomedical research to developing countries, and the prominent role of a poorly regulated pharmaceutical companies that provide funding, practitioners are being drawn into human subject research with little if any knowledge about their duties to prevent exploitation of the public in the name of science.

Provision of healthcare and biomedical research which is necessary for advancement of science must be understood as inherently ethical undertakings and not merely technical and mechanical in nature. Patients and research subjects are generally among the most vulnerable in society, whether through their illness, lack of information about their rights, paucity of scientific knowledge, or in the case of Pakistan due to poverty and existing hierarchical social structures. Those in white coats are still largely perceived as saviors and trustworthy advocates for public welfare above all other interests.

But the world is changing and this kind of unquestioning trust in healthcare professionals is on the wane. The early beginnings of this shift are also becoming evident in Pakistan as judged by increasing reports, some exaggerated, of unethical clinical practices and research. It is therefore essential that those in the role of imparting dental and medical education to the next generation take steps to ensure that they incorporate knowledge of bioethics with that of science and technical skills. But didactic teaching of bioethics by itself is not enough. Those who shoulder the task of teachers should also reflect on the

²Farhat Moazam, Aamir M. Jafarey, "Pakistan and biomedical ethics: Report from a Muslim country," *Cambridge Quarterly of Healthcare Ethics*, vol. 14, no. 03 (2005): 249–255.

importance of serving as good role models who students perceive as individuals with integrity and learn to emulate.³

“Guidelines and Teachers Handbook for Introducing Bioethics to Medical and Dental Students”

This document prepared by the HealthCare Ethics Committee (HCEC), a sub-committee of the National Bioethics Committee of Pakistan (NBC), offers broad guidelines to assist medical and dental college faculty in introducing ethics to their students. The aim should be to eventually move towards developing vertical and horizontal bioethics education incorporated into existing undergraduate curricula.

In preparing these guidelines, we are aware that there is no universal consensus on how bioethics should be taught, who should teach it, or how frequently it should be taught during undergraduate years. We also recognize that at present many Pakistani institutions lack trained “bioethicists” and sufficient infrastructures to formulate and implement a comprehensive ethics curriculum. However bioethics as applied to clinical practice and biomedical research is a practical discipline in which daily experiences of practitioners remain central. Discussion of the ethical issues inherent in cases encountered in clinics and hospital settings is universally accepted as among the best ways of instruction in this field.

These guidelines outline the basic concepts of bioethics which students should possess at the time of graduation. The document also suggests methodologies that have been found to be effective in teaching ethics, and offers tools that can be utilized to assess students. Care topics that should be incorporated in undergraduate medical education are elaborated upon with directions for their learning objectives and content outline. We realize that institutions vary in the way they structure their curriculum, however we recommend that *a minimum of 50 hours spread over 5 years be designated for bioethics education in an integrated fashion.*

We believe that dental and medical faculty with professional integrity, facing and recognizing ethical dilemmas in their own practice, and concerned about unethical practices by healthcare providing communities, are well situated to help their students learn to identify and reflect on these issues and discuss how they can be addressed to protect patients. Ethics is an intrinsic component of research, patient care and knowledge. An understanding of this fact can be developed using some of the time allocated to teaching sessions during clinical rotations. Using this document can serve as the first, much needed step leading eventually to a comprehensive, integrated ethics curriculum as faculty becomes more adept in imparting this knowledge.

³Frederic W. Hafferty, “In search of a lost cord: Professionalism and medical education’s hidden curriculum,” *Educating for Professionalism: Creating a Culture of Humanism in Medical Education* (2000): 11-34.

Competencies, Objectives, Teaching and Assessment

Broad Competencies to be Achieved Based on Knowledge, Skills and Attitudes

- Discourse
 - Appreciate basic principles of bioethics
 - Discuss bioethical issues with reference to principles of bioethics in social, cultural and religious perspectives
 - Analyze ethical dilemmas in healthcare practice
 - Demonstrate awareness of personal ethical standards and ability to avoid potential ethical conflicts with pharmaceutical industries and other health industry providers
 - Appreciate importance of respectful conduct with patients, staff and colleagues
- Research skills
 - Identify ethical concerns in research activities involving human subjects
- Communication skills
 - Communicate bioethical concerns to public and professionals logically with moral reasoning
 - Provide counseling to patients in a way that reflects understanding of ethical principles

Broad Objectives

At the end of five years MBBS or four years BDS program, students should be able to

- Identify and analyze common ethical dilemmas that arise within dental/medical clinical practice and in provision of public/community health care
- Identify and respect the rights of patients/families and recognize professionals' duties
- Recognize conflicts that can arise between patients and professionals in clinical practice and research
- Rationally analyze different moral positions on the same issue
- Construct moral arguments to support their own position
- Demonstrate professional behavior which includes respect for others, compassion, empathy, a reflective approach, and tolerance in their conduct towards patients, families, and colleagues
- Communicate clearly and effectively with colleagues, patients and their families

Suggested Modes of Teaching

- Ethics teaching is best performed in a stimulating and relaxed environment. The students should be ready to share their views and experiences and learn from each other
- The teacher/ facilitator should make sure that students discuss issues and try to understand different perspectives, whether they agree with these, or not
- The sessions for bioethics can be spread over the first to fifth year of college within different subjects or clinical rotations. For example the sessions for informed consent can be dealt with during clinical rotations while mental health ethics can be taught with the psychiatry course (suggestion on the placement of course is given below with the list of topics, for the college/ university curriculum committee). However, ethics should not be seen as in silos, and its education should be integrated within all clinical specialties

Following are a few teaching modes that can be used for active bioethics learning:

a) Interactive lectures

These are lectures with planned active participation of students attending the lecture. The lecturer breaks the lecture at least once per session to have students participate in an activity that lets them work directly with the information given. The activities capture and maintain student attention

and allow students to apply what they have learned and provide feedback to the instructor on their understanding. This participation is usually in the form of direct questions and answers or students tasks to be completed during the session.

- b) Small group discussions
Case discussions in small groups of 8 – 12 students are an effective method for teaching bioethics. The method increases students' moral reasoning skills.
- c) Teaching videos
Audiovisual material provides a rich medium for teaching and learning. Teaching videos on bioethical issues can effectively communicate complex information, introduce different ethical and moral perspectives and elaborate dilemmas with context. The videos can be used for understanding different situations and generating discussions in a classroom.
- d) Student Seminars
Classroom seminars where students or groups of students prepare and deliver their presentations on pre-decided topics can be an effective and enjoyable learning experience in bioethics. This method of learning provides opportunities for conceptual learning on the given topic, team work and communication skills.
- e) Role play
Engaging students in role play promotes active learning. Planned and structured role plays can be used to deliver components of the bioethics curriculum. Role plays involve learning with self-analysis, reflective practice, feedback and communication abilities.

Suggested Student Assessment Tools

Considering the importance of ethics and professionalism in day-to-day medical practice, ideally a separate bioethics assessment should be conducted before graduation, which should be mandatory for all students. However, an alternative approach is to incorporate bioethics questions within the existing examination system, for example, giving a few MCQs, SEQs and/or OSCE with clinical subject assessment in the final year.

Following are some of the tools that can be used for formative/ summative bioethics assessment:

- a) Multiple Choice Questions (MCQs)
- b) OSCE station in final professional exam
- c) Short Essay Questions (SEQ/LEQ)
- d) Observed Role-Play
- e) Discussion participation

Resources and Tools for Faculty Teaching

Tools for bioethics teachers have been incorporated in this document as resource for educators. The document includes case scenarios, links to relevant videos, references and useful reading material. All materials included in this document as teaching resources are either from the Creative Commons whose original sources have been duly acknowledged, or are reproduced with full permission of the publishers. These are by no means exhaustive and we encourage facilitators to refer to other resources available locally and through the internet. Links have also been included to teaching videos on bioethical issues, a good way of engaging students and being used by different institutions in Pakistan.⁴

⁴Teaching videos. <http://siut.org/bioethics/CBECProduction.html>.

Faculty Training

In order to teach effectively, faculty members involved in bioethics sessions should ideally be trained to enhance and refine their own understanding of the subject. Formal bioethics training will also enable them to learn different pedagogical methods, like role play and video, appropriately and effectively. Such training can be achieved through attending bioethics workshops, seminars and conferences that are now not uncommon in Pakistan. Institutional and departmental heads should encourage and support faculty and consultants who are interested in teaching bioethics.

Course Topics

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Course Specifications

1 - Introduction to Bioethics

Suggested Placement - Year 1 and 2

Title	Introduction to Bioethics
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Name available codes of ethics for healthcare professionals and their characteristics • Outline PMDC Code of Ethics for Medical and Dental Practitioners • Understand evolution of contemporary bioethics, its characteristics and relevance to research and practice
Content outline	<p>1) <i>Professional Codes</i></p> <ol style="list-style-type: none"> a. Introduce the Hippocratic Oath (5th Century BCE), basis of modern oaths administered to medical graduates. Discuss characteristics: Made by physicians for physicians, religion based, focus on physicians' character, virtues and duties to patients (beneficence).⁵ (Hippocratic Oath) b. Introduction to features of PMDC Code of Ethics⁶ (PMDC code of ethics) for Medical and Dental Practitioners and its requirement for bioethics education at undergraduate and postgraduate levels; other codes of ethics such as that of American Medical Association may be discussed. Please refer to PMDC code, in the handbook. <p>2) <i>Contemporary (modern) Bioethics (CB)</i></p> <ol style="list-style-type: none"> a. Understanding the beginnings of CB in the 1970s in USA to address ethical dilemmas raised by rapid advances in medical science and biotechnology. b. Defining characteristics (different from traditional codes): Universalist; product of multiple disciplines (philosophy, law, sociology, humanities, medicine including public health, etc.); centers on patients' right to be informed and make own decisions rather than on physicians' duties, opposes "paternalism" by physicians. c. Knowledge of four principles - autonomy, beneficence, non-maleficence, and justice.⁷ Understands autonomy in local societal and religious context. d. Understanding of Components of contemporary bioethics (an introduction; individual components will be expanded/repeated using real cases during suitable clinical rotations) <p>3) <i>Clinical Ethics</i></p> <ol style="list-style-type: none"> a. The virtues (character) expected from healthcare providers b. Rights of patients and duties of healthcare professionals c. Ethical basis and importance of informed consent d. Centrality of patient privacy and confidentiality e. Recognize and understand ethical issues arising during daily patient care in hospitals and outpatient clinics

⁵ Hippocratic Oath http://www.nlm.nih.gov/hmd/greek/greek_oath.html.

⁶ PMDC code of ethics:
<http://www.pmdc.org.pk/LinkClick.aspx?fileticket=v5WmQYMvhz4%3D&tabid=102&mid=554>.

⁷ Tom L. Beauchamp, James F. Childress, "Principles of biomedical ethics," *Oxford University Press, USA* (2001).

	<p>f. Ethical dilemmas when patients, families, and physicians disagree on patient management</p> <p>g. Debates around end of life decisions (E.g. ventilator dependent patients, euthanasia, etc.)</p> <p>h. Reproductive technologies (ovum donation and surrogacy)</p> <p>4) <i>Research Ethics</i></p> <p>a. Understanding the importance of human subject research for societal welfare but without exploiting subjects</p> <p>b. Familiarity with terms such as vulnerable populations, exploitation, coercion</p> <p>c. Knowing the stringent informed consent requirements</p> <p>d. Necessity for approval of research proposals by Ethical Review Committees prior to their undertaking</p> <p>5) <i>Public Health Ethics</i></p> <p>a. Understanding differences between hospital versus public healthcare services</p> <p>b. Knowing terms such as quarantine, compulsory vaccination, etc.</p> <p>c. Introduction to ethical tensions between balancing rights of individual citizens and harm to society</p>
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2.1 - Clinical Ethics

Suggested Placement - Relevant clinical rotations

Title	Informed Consent for Clinical Intervention
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Describe ethical and legal rationale for taking informed consent • Explain the process of consent-taking for clinical intervention • Identify common flaws in consent process and forms • Take informed consent for common intervention
Content outline	<ol style="list-style-type: none"> 1) Knowledge and understanding of legal and ethical basis of IC 2) Essential elements of IC - information, comprehension, and voluntariness of patient 3) Who takes IC and why; understand that person responsible for the treatment/intervention has primary responsibility for IC but multiple people may be involved in explaining and documenting it 4) Who gives consent and why; understand legal and ethical requirement that IC signed by adult, competent patient regardless of gender, education, social standing 5) Understand terms mental incompetence and minors and role of family member, guardian/surrogate in IC in such cases 6) Family influences on IC process: Recognize influence of cultural norms (hierarchical/androcentric systems, position of women in family, discrimination against disabled, etc.) as hurdles to ethical IC and be able to negotiate these sensitively. Relevant teaching material in appendix: Video “To tell or not to tell”, and examples of good and bad consent forms. Appendix section 2: Cases. Appendix section 2: Example of a good and a bad informed consent document 7) Understand patient’s “best interest” principle in emergency situations; familiar with option of two physicians providing permission for intervention in incompetent patients when family is not available

2.2 & 2.3 - Clinical Ethics

Suggested Placement - Relevant clinical rotations

Title	Privacy, Confidentiality and Truth Telling
Objectives-	<p><u>Privacy and Confidentiality</u> Students should be able to</p> <ul style="list-style-type: none"> • Discuss the terms privacy and confidentiality • Appreciate the importance of privacy and confidentiality in clinical practice <p><u>Truth Telling</u> Students should be able to</p> <ul style="list-style-type: none"> • Appreciate the importance of truth-telling in clinical practice • Recognize issues that can arise from breaching the principle of truth-telling
Content outline	<p><u>Privacy and Confidentiality</u></p> <ol style="list-style-type: none"> 1) Knowledge of privacy and confidentiality; differences between the two concepts with examples 2) Their importance in clinical settings – respect for persons, covenant of trust between patients and their physicians 3) Dangers of violation of privacy and confidentiality 4) Understand when it is ethically justifiable to breach confidentiality 5) Issue of balancing patient’s right to confidentiality versus possible harm posed to others. Appendix Section 3: Case of homicidal patient confiding in psychiatrist about intention to kill someone <p><u>Truth Telling</u></p> <ol style="list-style-type: none"> 1) Understanding this concept rests on respect for persons (patients), to build trust and rapport, perceive them as partners in decision making and care plans; ethical and legal basis 2) Recognize challenges to concept in family centered societies where families wish to protect ill kin and are responsible for their medical care 3) Understand possibility of harm to some patients through deception and others by full disclosure 4) Learn to negotiate what and how to communicate truth to patient while respecting family desire to protect patient

2.4 & 2.5 - Clinical Ethics

Suggested Placement - End of Life - Relevant clinical rotations

Suggested Placement - Reproductive Ethics – Obstetrics and Gynecology, Pediatric rotations

Title	End of Life Issues and Reproductive Ethics
Objectives	<p><u>End of Life Issues</u> Students should be able to</p> <ul style="list-style-type: none"> • Appreciate the need for discussing end-of-life decisions in clinical practice • Identify potential dilemmas and conflicts in end-of-life clinical situations • Attempt to analyze dilemmas in end-of-life clinical situations, when patients, families and physicians have different opinions <p><u>Reproductive Ethics</u></p> <ul style="list-style-type: none"> • Define the terms “in-vitro fertilization” and “surrogacy” • Outline the potential ethical issues related to surrogacy • Discuss the implications of surrogacy from social, moral, legal and religious perspectives

	Discuss Pakistani laws related to termination of pregnancy
Content outline	<p><u>End of Life Issues</u></p> <ol style="list-style-type: none"> 1) Understand medical futility and prolonging dying versus prolonging life 2) Capability to identify, analyzes, and handles ethical dilemmas due to disagreements between patient and family, and family and healthcare professional due to different values. 3) Comprehend concepts of withdrawal versus withholding treatment; understand the ethical difference between not instituting life /prolonging interventions (such as ventilation) as opposed to withdrawing these when medical care judged to be futile; family role in making such decisions 4) Understand the concepts of brain death and persistent vegetative state; how these are determined and differences between the two medically, legally and ethically 5) Understand what Do Not Resuscitate (DNR) means and includes; when, why and how this decision is taken; recognize the family’s important role in such decisions 6) Breaking bad news and communication skills: Learning and practicing empathy and compassion, listening skills, and shared decision making; understand patient and family concerns, and how to deal with their emotional and psychological stress in the face of terminal illness <p><u>Reproductive Ethics</u></p> <ol style="list-style-type: none"> 1) Understand basic science behind in-vitro fertilization (IVF) and connected ethical issues; IVF with sperm and ova of a heterosexual married couple versus the use of donated sperm and/or egg 2) Know ethical debates supporting and opposing sale of donor eggs and those donated altruistically 3) Comprehend ethical and medical pros and cons of surrogacy; issue related to using women, especially from poor developing countries, as paid surrogates - risks versus benefits to them; rights and best interest of a child conceived in this way and those of gestational (surrogate) mother and couple contracting with her 4) Discuss role of religious scholars, including <i>ulema</i>, regarding use of IVF and surrogacy by infertile couples 5) Have awareness of different positions within Muslim schools of jurisprudence regarding termination of pregnancy, including permissibility and impermissibility opinions.

2.6 - Clinical Ethics

Suggested Placement - Medicine, Surgery and Oncology Rotations

Title	Euthanasia
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Define the term Euthanasia and types of Euthanasia • Discuss the role of Euthanasia in clinical practice • Debate the implications of Euthanasia from social, moral, legal and religious perspectives
Content outline	<ol style="list-style-type: none"> 1) Knowledge about types of euthanasia for patients - active, passive, voluntary, involuntary – and concept of physician assisted suicide, and ethical debates connected to each; awareness of “Dignitas” and similar initiatives in countries that allow euthanasia

	<p>2) Be familiar with rational (secular) arguments for and against euthanasia: For - individual's right to make decisions about himself/herself, end unrelenting suffering, allow death with dignity when further treatment is futile. Against – contrary to professional ethical code to save not end life, abetting suicide/murder, “playing God”</p> <p>3) Awareness of common religious (including Muslim <i>ulema</i>) arguments opposing euthanasia and the reasons behind these</p>
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2.7 - Clinical Ethics

Suggested Placement – Relevant Clinical Rotations

Title	HIV and Sexually Transmitted Diseases, HBV and HCV
Objectives	<p>Students should be able to -</p> <ul style="list-style-type: none"> • Discuss the term “stigma” and “social discrimination” • Recognize the role of a healthcare provider in protecting their patients from stigma and social discrimination • Discuss the potential issues and implications of screening from social and moral perspectives
Content outline	<ol style="list-style-type: none"> 1) Understand importance of privacy and confidentiality in dealing with such patients; risks of stigmatization and social discrimination; 2) Balancing duty to patient's welfare versus possible harm to sexual contacts and cultural contexts influencing this 3) Familiarity with ethics of screening and testing high risk patients and populations; issues of informed consent and counseling of those being screened; professional responsibilities to those testing positive on screening versus to the larger community

2.8 - Clinical Ethics

Suggested Placement – Public Health and Relevant Clinical Rotations

Title	Resource Allocation
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Define the terms “resource allocation” and “social inequalities” • Discuss the importance of appropriate resource allocation in healthcare • Recognize the role of a healthcare provider in resource allocation
Content outline	<ol style="list-style-type: none"> 1) Understand how limited resources and services (trained professionals, ventilators, ICUs, etc.) and social inequalities (poverty, illiteracy, gender, etc.) lead to ethical dilemmas and inequities in existing healthcare. For teaching cases please see appendix. 2) Comprehend the tensions between preventive versus curative medicine, public versus individual health services; funding priorities between primary and tertiary care

3 - Medical Error

Suggested Placement – Medicine and Surgery Rotations

Title	Medical Error
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Differentiate between medical error and negligence • Discuss different types of errors, possible reasons for their occurrence and responsibility of individual and system to avoid them

	<ul style="list-style-type: none"> Recognize the importance, methods and difficulties in disclosure of errors
Course outline	<ol style="list-style-type: none"> 1) What are medical errors? How are they classified? 2) How errors in medical practice can be prevented? Role of the system and the responsibility of the individuals 3) How to disclose errors? Why is disclosure ethical and why these are not disclosed.

4 – Using Patients for Education and Training

Suggested Placement – Relevant Clinical Rotations

Title	Teaching, Training and Patient Care Ethics
Objectives	<p>Students should be able to appreciate and discuss ethical dilemmas related to -</p> <ul style="list-style-type: none"> Consent for examination (non-intimate/ intimate) Consent for performing procedures (drawing blood, administering injections/ IV lines, lumbar puncture etc.) Examining or performing procedures on the anesthetized patient Patient’s privacy and confidentiality
Content outline	<ol style="list-style-type: none"> 1) Role of and issues related to real patients vs. simulated patients in medical teaching 2) Professionalism for the medical trainee; respect and gratitude towards patients; patients’ right to refuse examination by medical students 3) Patient’s privacy and confidentiality with respect to medical teaching 4) Respect for unconscious patients, dead bodies and human body parts/ specimens

5.1 & 5.2 - Organ Transplantation Ethics

Suggested Placement – Nephrology and Urology rotations

Title	Organ Transplantation Ethics
Objectives	<p>Students should be able to -</p> <ul style="list-style-type: none"> Discuss Ethical issues in live, related organ donation including exploitation of family members Explore Ethical and legal issues in organ sale Discuss challenges in deceased organ donation Demonstrate their understanding of concept of brain death versus cardiorespiratory death
Content outline	<ol style="list-style-type: none"> 1) Introduction to science and technology of living, related organ donations are regarded as the most favorable donations having the least ethical issues; existing ethical issues in living, related donations and how exploitation, coercion and familial pressures can come into play; process of careful scrutiny of family donors, and why 2) Understanding ethical issues in living unrelated organ donation and organ sales and their linkage with exploitation. Understand how the rich benefit and why this is not a “win-win” situation as promoted 3) Familiarity with Pakistan Organ Transplantation law⁸ 4) Familiarity with science and process of obtaining organs following

⁸The transplantation of human organs and tissues: an ordinance. Ordinance Gazette of Pakistan, Government of Pakistan, 2007 (XLIII of 2007). <http://tx-society-pk.org/transplant%20law.pdf>.

	<p>death</p> <p>5) Deceased donation and concept of brain death; how it permits organ harvesting from consenting donor, declared brain dead but with heart still beating and circulation intact; comparison with conventional cardiopulmonary death where organ is removed from deceased donor</p>
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6.1 & 6.2 - Ethics of Physician Pharmaceutical Interactions

Suggested Placement – Relevant clinical rotations

Title	Ethical Issues and Guidelines
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Discuss ethical issues related to physician- pharmaceutical interaction • Identify possibilities of conflict of interest (COI) in clinical scenarios • Suggest ways of handling COI • Appreciate global recognition of COI issues
Content outline	<ol style="list-style-type: none"> 1) Familiarity with PPI guidelines of NBC regarding appropriate interactions with industry. 2) Ethical tensions in congresses, conferences, seminars sponsored by industry including scientific content, travel and accommodation arrangements, social activities. 3) Partnership in pharmaceutical companies and influence on prescribing habits. 4) Industry sponsorship of clinical trials. 5) Discussion of Pakistani cases

7 - Human Subject Research Ethics

Suggested Placement – Community / Family Medicine

Title	Human Subject Research Ethics
Objectives	<p>Students would be able to</p> <ul style="list-style-type: none"> • Discuss the historical background and origins of common research ethics guidelines (Nuremberg code, Helsinki, CIOMS, Nuffield council etc) • Demonstrate understanding of the elements and process of informed consent in research, differences between clinical care and clinical research and its effect on participants (therapeutic misconception), concept of vulnerability in context of research and the necessity of additional safeguards to protect vulnerable population • Define standard of care and discuss its issues in developing countries • Recognize the influences of pharmaceutical industry in the research enterprise and concept of ‘conflict of interest’ in research setting • Relate to contemporary issues in genetic research especially issues related to confidentiality of individuals and race • Identify issues related to stored tissue samples and their subsequent usage for research
Content outline	<ol style="list-style-type: none"> 1) Importance of research in medicine. 2) Clinical trials and its phases. 3) Ethical issues in human subject research and historical land marks

	<p>a. Ancient history b. Nuremberg code, Helsinki, CIOMS, Nuffield Council, NBC 9,10,11,12,13</p> <p>4) Respect for human subject in research, role and procedure of consent (some duplication with clinical ethics) 5) Concept of Justice especially distributive and assessing risk and benefits for the human subject in research 6) Introduction to the term “Therapeutic Misconception” to understand the difference between clinical care and research and role of physician and researcher 7) Vulnerability with main emphasis in research. Highlighting ethical issues in children, neonates and unconscious patients 8) Role of Pharmaceutical industry in research enterprise and how the “conflict of interest” affects research. (some overlap with Pharma-physician issues in clinical ethics) 9) Ethics Review Committee (ERC) why is it needed? history, importance, composition and working (process of review) 10) International guidelines on research ethics, especially genetic research and issues related to race, incidental findings and confidentiality 11) Storage of tissue samples; consent for their usage for different research and export to other institutions or countries 12) Review of mock research proposals</p>
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8 - Public Health Ethics

Suggested Placement – Community / Family Medicine

Title	Public Health Ethics
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Differentiate between the ethical approach to individual patient and public health • Recognize the dilemma between individual rights/freedom and “greater good” • Identify doctor’s responsibility to improve or protect the environment • Identify and discuss environmental issues like global warming, pollution, deforestation, urbanization, food insecurity, safe water supply etc. from an ethical perspective emphasizing respect for nature and the habitat of wildlife and Man.
Content outline	<p>1) Define public health ethics and differentiate it from clinical ethics 2) Concept of “utilitarianism” and how it conflicts with individual rights (Concept of greater good for greater numbers) using examples like smoking and obesity 3) Discuss when, how and why individual rights can be compromised 4) Discuss the ethical issues faced in Quarantine and forced vaccination programs with reference to public health diseases like polio, measles,</p>

⁹ The Nuremberg Code: <http://www.hhs.gov/ohrp/archive/nurcode.html>.

¹⁰ WMA Declaration of Helsinki: <http://www.wma.net/en/30publications/10policies/b3/>.

¹¹ CIOMS Guidelines: http://www.cioms.ch/publications/layout_guide2002.pdf.

¹² Nuffield Council on Bioethics Guidelines: <http://www.sirc.org/news/nuffield.shtml>.

¹³ National Bioethics Committee guidelines for stem cell: Research
http://www.PHRC.org.pk/stem_cell_protocol.htm

	<p>SARS, HIV/AIDS etc.</p> <p>5) Discuss the ethical issues faced by health care professionals in disasters like floods and earthquakes related to limitation of resources, emergency care, research and rehabilitation programs.</p> <p>6) Discuss ethical issues faced by law forming bodies and its health care collaborating partners in implementation of a public health policy for society.</p> <p>7) Discuss moral relationship between human beings and the environment (How and why should we value nature?)</p>
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9 - Plagiarism and Scientific Misconduct

Suggested Placement – Community / Family Medicine

Title	Plagiarism and Scientific Misconduct
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Demonstrate understanding of different types of “Plagiarism” and “scientific misconduct” related to research and publication • Describe the concept of “intellectual property” in relation to medical writing • Identify issues related to authorship criteria for scientific journals
Content outline	<ol style="list-style-type: none"> 1) Plagiarism and scientific misconduct as ways of lying, stealing or cheating 2) What is intellectual property? And who owns it with reference to research ideas, proposals, data, publication manuscripts etc 3) Whose names should be published as authors and how to decide the sequence? Authorship criteria of different journals.

10 – Ethics of Mental Healthcare

Suggested Placement – Psychiatry

Title	Introduction to Mental Healthcare: Ethical Issues
Objectives	<p>Students should be able to</p> <ul style="list-style-type: none"> • Discuss the ethical and legal challenges of the mentally ill and how they are different from those with physical illness with emphasis on their vulnerability and the risks involved.
Content outline	<ol style="list-style-type: none"> 1) Discuss how the needs of the mentally ill are different from those with physical illness (with emphasis on the concept of consent/capacity; confidentially/sharing of information; working with the families; risk assessment etc) in the context of legal, socio-cultural and religious factors in Pakistan.

1: Introduction to Bioethics

No.	Title	Page
1	Aamir Jafarey, "Bioethics: Challenging the new normal," <i>Paramount Textbook of Preventive Health and Community Medicine</i>, chp. 1 (2015): 1-26	18
2	The Hippocratic Oath	42
3	Pakistan Medical & Dental Council Code of Ethics of Practice For Medical and Dental Practitioners	44
4	Farhat Moazam and Aamir M. Jafarey, "Pakistan and biomedical ethics: Report from a Muslim country," <i>Cambridge Quarterly of Healthcare Ethics</i>, vol. 14, no. 3 (2005): 249 – 255	63

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Aamir Jafarey, “Bioethics: Challenging the new normal,” *Paramount Textbook of Preventive Health and Community Medicine*, chp. 1 (2015): 1-26.

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Bioethics: Challenging the New Normal

Aamir M. Jafarey

Introduction

The objective of this chapter is to introduce the readers to the basic concepts of bioethics, with a focus on biomedical ethics. This will possibly be the first exposure to this field for many readers, which is why the discussions have been kept very basic. The chapter describes several key bioethical concepts to the reader, but does not aim at providing an exhaustive overview of a very broad, multidisciplinary field. By the end of this brief chapter, it is hoped that the readers will gain familiarity with this discipline and feel stimulated to delve deeper into specific areas of interest independently.

The chapter will begin with a brief historical overview of bioethics. This will lead into a discussion on the evolution of contemporary bioethics and its dominant paradigm called ‘Principlism’. This section will also discuss the main criticism leveled against this particular approach. As it has evolved, several distinct branches of contemporary bioethics have also taken shape, each a result of historical events and developments in the field of biomedicine. The three major themes for this chapter are Research Ethics, Clinical Ethics and Public Health Ethics and each will be discussed in detail in subsequent sections. A section is devoted to the ethical debates around organ transplantation, with a particular focus on the development of the current law on tissue and organ transplantation in the country. Ethical issues in physician-pharmaceutical interaction, which is now a recognized global concern, as well as emerging ethical challenges posed by biotechnological advancement and environmental issues, will also be addressed briefly in additional sections. Pertinent examples will be given, whenever possible from within the Pakistani context, to illustrate the points under discussion. Similarly, paradigm legal cases will also be discussed as they have helped develop ethical debates on a number of issues. These cases are generally from the US legal system because of an established history of medical litigation there. There are no examples to quote from the Pakistani legal system since cases do not make it to litigation, and even those that do are generally settled out of court.

From the Hippocratic Oath to Contemporary Bioethics

The term bioethics was first used in 1927 by Fritz Jahr in Germany in context of moral obligations towards all forms of life, human as well as non-human. The term and the concept of bioethics remained dormant in the decades that followed and was again resurrected by Van Rensselaer Potter II, an American biochemist in 1970. Potter used the notion of bioethics to study the linkage between humans and their interaction with the ecosystem. At about the same time, in 1971 the Kennedy Institute of Ethics was inaugurated in Georgetown University Washington DC, with Andre Hellegers as the founding Director. Hellegers and the Kennedy Institute steered bioethics towards a distinct biomedical ethics bearing for the first time, a direction in which it continues to progress.^{1,2}

Unlike the hard sciences, no one particular definition adequately encapsulates this field. Bioethics can be described as a discipline dealing with the ethical and philosophical implications of biological advances and their applications on living beings. For the purpose of this chapter, the focus of discussions will primarily be on bioethics and human health, that is biomedical ethics.

Although the concept of modern bioethics seems to have originated in the 20th century, with major advancements occurring only in the latter 3 decades of that century, the broad idea of ethical norms governing healthcare and research on human subjects has a much longer history. The Hippocratic Oath for healthcare professionals is a well-known document which dates back to the 5th century BCE. The original ethos of this oath, with modifications to suit needs of current times, still forms the basis of oaths administered to medical graduates across the world. Among Muslims, Ishaq bin Ali al-Ruhawi, a physician from Mesopotamia, who lived in the latter half of the 9th century CE, is credited with being the author of the first medical ethics book in Islamic medicine.³ Maimonides (1135-1204 CE), a Jewish rabbi, physician and philosopher, was the court physician to Sultan Salahuddin and is remembered for the ‘Prayer of Moses Maimonides’, an oath second only to the Hippocratic Oath.

Physicians have used these and similar documents to fashion guidelines to maintain ethical norms while dealing with their patients. Other modern documents and relevant cases and incidents will be referred to in subsequent sections of this chapter.

Contemporary Bioethics

Classically, physicians have been perceived to be the unquestionable ultimate decision makers in healthcare matters, with all others merely following orders. Even the original Hippocratic Oath strengthened this paternalistic practice. However, this notion of paternalism is looked down upon in contemporary bioethical teachings which strive to empower the patient, giving him or her the right to decide in healthcare decision-making and also in the voluntary participation in health research as a human subject.

The social changes taking place in the US in the late 1960s and 1970s had a significant influence on the trajectory of contemporary bioethics. Those decades in the US were a time of assertion of individuality, seeking rights for peripheralized groups including women, with anti- authority and anti-establishment movements. These were political movements against compulsory enlistment in the armed forces for the Vietnam War, the Afro- American movement demanding equal rights, the feminist movement seeking emancipation of women from male dominance, and so on. These had a profound effect on the way people were thinking with a common thread being stress on the importance of equality and freedom of choice. The atrocities committed by scientists of Nazi Germany on Jews and prisoners of war in the name of research during World War 2 (discussed later in this chapter) were also fresh in peoples’ minds. It is against this backdrop that contemporary bioethics began to take shape, with philosophers, theologians, lawyers and a few physicians in the lead.

One of the most influential texts in biomedical ethics, first published in 1997 and now in its 5th edition is the Principles of Biomedical Ethics by two US philosophers, Tom Beauchamp and Jim Childress.⁴ The authors formulated four principles, autonomy, beneficence, non-maleficence and justice as mid-level principles bridging moral theories and common morality. This approach, referred to as Principlism still remains the dominant paradigm within international ethics discourse. This form of ethical analysis, intended for philosophers as an aide to analyze ethical issues, rapidly became popular among those with no philosophical background including physicians.

However this approach has weaknesses. In the present form in which they are perceived, the four principles make no space for religion, society, community or the many diverse ways in which the ‘self’ is molded and how it interacts with ‘others’, making this framework alien and unworkable in many countries. In Pakistan, and for the 1.6 billion Muslims across the world, family and religion play a central role in how life is lived. This divergence between what is taught and what is being lived and practiced has cast a dense shadow on Principlism which has consequently come to be regarded as a theoretical exercise with little practical application. Principlism can therefore be problematic in its application and utility in many parts of the world and has been criticized for this reason even in the United States.

In Pakistan however, the four principles approach has been very popular in teaching bioethics since it packages the vastness of the subject into four neat categories. The principles based analytical framework for biomedical ethics is often ‘theoretical’, but with little or no ‘practical’ applicability within the Pakistani context. Even though the students are taught the four principles as the tool to navigate ethical dilemmas, when it comes to application, they often turn to local norms and religious values which perceive the individual as intricately enmeshed within the family. In the hands of healthcare related professionals with little or no philosophical grounding, Principlism is being used in an ‘over simplified, reductionistic,... mechanically applied way...’.⁵ These concerns certainly seem to have emerged as quite real in many parts of the world including Pakistan. Why and how Principlism morphed the way it did in so many parts of the world remains an interesting and important question that requires further research.

Therefore, although it is important to know about Principlism, it is equally important to realize its limitations in the local context. There can be no cookbook recipes or algorithm for ethical analysis, and any ethical analysis will have to take into account the context including the religious and cultural norms and practices for it to come to an acceptable conclusion.

Current status of Bioethics Education in Pakistan

The Aga Khan University at Karachi was the first institution to introduce bioethics in the undergraduate medical curriculum in the mid 1980s. Initially taught informally, the curriculum has since then been formally integrated into the various courses of the university. The subject is primarily being taught by healthcare professionals who have a personal interest in bioethics. The trend towards formal bioethics education also started from the same institution with several faculty members taking sabbatical time abroad for formal training through various bioethics programs.⁶

The first formal institutional framework for bioethics appeared in 2004, with the establishment of the Centre of Biomedical Ethics and Culture (CBEC) at the Sindh Institute of Urology and Transplantation (SIUT), Karachi. This centre remains the only example of institutional support for bioethics in the country since all activities of the CBEC are funded by its parent institute, the SIUT. In addition to organizing short courses and workshops on various bioethics related themes, in 2006 this centre initiated Pakistan’s first formal bioethics training program, a one year Postgraduate Diploma in Biomedical Ethics. Up till writing of this chapter, this program has trained 71 mid-career medical professionals from across the country to lead bioethics educational programs at their own institutions. In 2009 the CBEC initiated a two year Masters in the Bioethics program for a smaller number of people who will form the bioethics leadership of the country in the years to come. Both these programs continue to be Pakistan’s only indigenously funded bioethics programs. A Masters in Bioethics program was also initiated at the Aga Khan University in 2008, funded by a grant from the US National Institutes of Health. The program continued till 2012 when external funding ceased, and had trained about 70 individuals.⁷

Considering the increasing numbers of people with formal bioethics training, it comes as no surprise that there has also been an increase in bioethics conferences and thematic workshops in recent years across the country. Whereas up till 2006, bioethics related academic meetings had been organized only in Karachi, and that too at one institution, several institutions across Pakistan have now held workshops. These include not only major cities like Islamabad, Lahore and Peshawar but also institutions in smaller towns like Swat, Nawabshah and Jamshoro.

Several health sciences institutions have started both formal and informal bioethics education programs for medical students, nurses, medical technologists as well as residents in different specialist programs. However, despite this, most medical colleges still do not have formal inclusion of bioethics in their

curricula, even though the Pakistan Medical and Dental Council regulations stipulate this. The availability of adequately trained manpower should hopefully bring about a change in this scenario.

Pakistan also has a National Bioethics Committee (NBC), notified by the Ministry of Health.⁸ This committee is mandated to deliberate upon ethical matters of national importance and has also come up with guidelines such as for stem cell research and interaction between pharmaceutical companies and physicians.^{9,10} The Health Care Ethics Committee, a subcommittee of the NBC, has developed guidelines for teaching bioethics to medical and dental students, which can serve as a template to including a standard bioethics curriculum for medical and dental institutions.

Clinical Ethics

Clinical ethics deal with ethical issues that emerge during the medical care of a patient. One of the major contributions of contemporary bioethics has been to increase the awareness of the patients about their rights. This has brought into question the archaic practice of paternalistic medical practice, where the physician decided and the patient complied, unquestioningly.

There are certain core values that are central to ethical patient management, respecting the wishes of the patient being one of them. The following section will discuss some of these central concepts in clinical ethics.

Informed Consent

The current practice of obtaining informed consent from patients prior to any invasive procedure forms the cornerstone of ethical medical practice and is based on the value of respect for persons. An appropriate informed consent would involve having a discussion with the patient about the disease, the treatment options available, the alternatives if any, the possible side effects or complications of the treatment and the benefits of getting treated. The patient should also know the consequences of not opting for the recommended treatment. The patient's decision should not be coerced or influenced and should be taken only after the patient understands all the relevant aspects of the treatment being offered.

The practice of medical decision-making has significant cultural underpinnings. In many Eastern cultures such as Pakistan, the family often plays a key role, with the triad of physician, patient and family all involved in the process.¹¹ However, the inclusion of the family in the discussions should not be at the cost of the patient's exclusion.

In addition to this moral aspect of informed consent, there is also the legal aspect to consider. Several historic lawsuits influenced the need for a fully informed, understood and documented consent becoming a legal necessity before any invasive interventions could be undertaken. In one of the earliest recorded medical lawsuits, an English patient, Slater, in 1767 sued his surgeons, Baker and Stapleton, for intentional refracturing of his healing tibia rather than the agreed-upon dressing change. In its ruling the court said that the physicians were culpable since they had not 'informed' the patient about the treatment plan. They made no mention of the need for the patient to actually agree to the plan.¹² In another landmark case in 1914, Schloendorff sued the Society of New York Hospitals because her surgeon operated on her uterine fibroid rather than limit himself to just performing the agreed upon examination under anesthesia. The court ruled that 'every human being... has a right to determine what shall be done with his own body' and found the surgeon guilty of assault. This became the first ruling where a patient's will was deemed to be legally overriding the surgeon's opinion in medical treatment.¹³ Pakistani law also stipulates that a fully documented informed consent should be obtained from the patient before performing any invasive medical procedure. In the case of an adult of sound mind, whether male or female, consent has to be obtained directly from the patient, and not from a relative. The observed practice however is different. For instance, it is commonly seen that in case of a female patient, the informed consent form is offered for signature not to the patient but to her father, husband or son. This

may be common practice, but is neither legally valid nor morally sound. A study looking at the practices of physicians at a Pakistani medical university also showed that the focus of attention for the process of informed consent shifts away from the patient in the Pakistani milieu.¹⁴ However, while respecting family traditions, it is important for physicians to bring the patients into the decision making process and providing an opportunity for them to be heard.

Respect for Privacy and Confidentiality

Issues of privacy and confidentiality also form part of the spectrum of respect for the patient. Privacy pertains to the control of sharing access to oneself with others either physically, behaviourally or intellectually. For instance, the availability of a private space for consultation and examination of the patient is an essential requirement in medical practice. It is the responsibility of healthcare institutions to provide such space like examination rooms or a curtained enclosure. Confidentiality is related to the information provided by the patient in the course of care to the physicians in a relationship of trust, and with the expectation that it will not be shared with anyone without permission. A common breach of this trust is witnessed when physicians discuss patients informally among each other in public spaces like hospital elevators, cafeterias and now even on social media like Facebook. Another area of breach of confidentiality is the patients' medical charts being accessed by people who are not directly concerned with the patients' medical care. Contemporary notions of bioethics put great emphasis on the importance of privacy and confidentiality.

However, confidentiality of medical information is not absolute. There are times when confidentiality can be ethically and legally breached. A paradigm case in this area is the Tarasoff case from the United States. In 1969, a university student under treatment of a psychiatrist informed his doctor of his intent to kill a fellow student whom he identified as Tatiana Tarasoff. The psychiatrist did not report the threat to the authorities, treating it as confidential information. The patient went ahead and killed Tarasoff. Subsequently the parents of the deceased student sued the doctor for not having informed them or the authorities of this identifiable danger to their daughter. The doctor pleaded patient confidentiality but the court ruled that confidentiality was not absolute and that 'the protective privileges end when public peril begins'.¹⁵

Ethics Related to End of Life Decisions

Contemporary bioethics discourse has been dominated by ethical issues concerning situations at the extremes of life, especially those around the end of life scenarios. The two cases discussed below are regarded as paradigm cases which highlight many aspects in the end of life debate.

Among the first court cases to leave a lasting impact on the shaping of clinical ethics practices was the Karen Quinlan case. In 1975, Quinlan, a 21 year old girl from New Jersey, USA collapsed at a party, presumably under the influence of drugs and alcohol. She required ventilator support and subsequently went into Persistent Vegetative State (PVS), a condition in which the patient is in deep unconsciousness that is almost always irreversible. Her nutrition was maintained through tube feeding. After several months of no visible improvement, Quinlan's family members wished that since there was no hope of recovery, her ventilator be removed so that she may die. A legal battle ensued since the physicians and the hospital refused to comply with the family wishes. The local court ruled that since Quinlan was not brain dead, the ventilator could not be removed. The case then went to the New Jersey State Supreme Court which subsequently ruled that it was the right of the family of the dying, incompetent patient to decide to let the patient die after removal of the ventilator. The court also opined that hospitals should have committees to look at such cases which should be decided therein and not come to the courts.¹⁶ This set the stage for the development of Hospital Ethics Committees at hospitals, discussed in a subsequent section of the chapter.

The Quinlan case was an example where the ethical dilemma revolved around the question of what constitutes life, what is a life worth living, and quality of life issues. Such end-of-life cases also raise the issue of whether extraordinary medical measures are prolonging life or whether they actually prolong the process of dying. In this particular case the family wished to withdraw support and let her die, whereas the physicians were against removing the ventilator.

Another paradigm case was that of Nancy Cruzan of Missouri, USA, which led to the landmark judgment by the US Supreme Court in 1990, that recognized the right of dying patients. This ruling has had a lasting impact on similar cases in the US. Cruzan, at the age of 24 was involved in a car crash and ended up with severe brain injuries and ultimately PVS. The family's desire to remove the feeding tube (Cruzan was breathing on her own, and unlike Quinlan was not on a ventilator) was granted because there was evidence brought forward by her friends that she had made her wish clearly known for her life not to be supported artificially, if such a situation arose. This paved the way for the concept of advance directives which are now an established legal means for a person to leave specific and legally binding instructions regarding his or her medical care if the person is rendered incapable of taking decisions.

End of life ethical conflicts may be because the family wishes the care providers to 'do everything' while the physicians feel that the treatment is futile, or the reverse, with the family wanting to withdraw support from a patient whom physicians may consider salvageable. Both situations can be very complex, both morally as well as legally.

One of the main focuses of clinical ethics has been the centrality of the patient's wishes in his or her treatment. This is based on the principle of individual autonomy which rests on the broader moral value of respect for the individual. The patient's wishes have to be kept central in the decision-making process. In situations when the patient is incapable of expressing his or her wishes, as in the aforementioned examples, the patient's prior wishes as expressed through advance directive or will should be considered. In the absence of such a document, what are perceived to be the patient's wishes matter in the decision making process.

In clinical practice in Pakistan and also elsewhere, serious conflicts are seen to arise when the family wants to act against the previously expressed wishes of an incapacitated patient. Such challenges tax the healthcare provider's ability to negotiate with families to resolve conflicts with the best interest of the patient foremost. In Pakistan, legal recourse to address such conflicts exists only theoretically, and since no case has been taken to court, there are no legal paradigm cases.

Euthanasia and physician assisted dying is another aspect of the end of life debate that evokes emotions in contemporary bioethical debates. These are considered for patients who are in terminal stages of their diseases like advanced cancer, or are in extreme suffering due to an untreatable condition from which recovery is highly unlikely to occur, such as quadriplegia. Euthanasia is when death of a patient is deliberately brought about by a health professional, with or even without the prior consent of the deceased. On the other hand, physician assisted dying is when the health professional provides the means of termination of life to the patient who then uses it to take his or her own life. Those supporting such measures base their arguments on the importance of realizing the inevitability of death in such extreme situations and therefore the desire to bring about a 'dignified', controlled and preplanned death. Those opposing such interventions talk about the sanctity of life, both sides making compelling arguments. At present euthanasia, under strict regulations and at the documented request of the patient, is legal in the Netherlands, Belgium and Luxembourg. Physician assisted dying also has legal sanction in these countries as well as in Switzerland and the states of Montana, Oregon and Washington, in the US, with other US states legislating on it currently.¹⁷ In the Pakistani context, as Islam prohibits the ending of one's own life or taking the life of another person, both physician assisted dying and euthanasia would be

against religious teachings and unlawful. Appropriately alleviating the suffering of those in terminal illnesses is a valid alternative which needs to be explored in such difficult situations.

Similar dilemmas are also common at the beginning of life. For instance, what constitutes life, and when does life begin are areas that have provided challenges for years. Also, under debate are questions such as what is a life worth living, and how does one decide whether a certain level of physical or cognitive disability is acceptable but another level of handicap merits abortion when detected on antenatal screening? This debate will be picked up in a subsequent section.

Hospital Ethics Committee

As can be expected, ethical questions frequently arise in healthcare delivery. The concept of creating Hospital Ethics Committees to provide assistance and advice for the resolution of such issues has evolved over the recent years and modern hospitals across the world are creating such bodies. These committees are mandated to receive consultations on ethical issues from hospital personnel, patients and their families. While trying to understand and resolve such conflicts, an ethics consultation generally takes into account several aspects of the case including medical perspectives of the case, patient preferences, quality of life issues and other relevant contextual features.¹⁸

These committees consist of hospital staff from different disciplines, including physicians, nurses, members of the hospital administration, often a lay member representing the community or patient perspectives, someone with a legal background and also a religious scholar. Although members need not have had any formal bioethics education, it is now becoming increasingly common to have at least a few members trained in bioethics to facilitate discussions. These committees offer ethics consultation services in response to requests regarding an ethical dilemma in the care of a patient. This consult can generally be raised by any member of the medical team or the patient or his relatives.

At present, Hospital Ethics Committees are a rarity in Pakistan. It is more common for hospital staff to provide ethical advice as and when needed, rather than a formally designated committee. Although this is less than ideal, in resource poor situations, this can be an effective means of addressing ethical issues in clinical care.

A variety of issues lead to ethics consults. According to one analysis, conflicts between different caregivers or between the caregivers and the family are most likely to trigger an ethics consult rather than other concerns.¹⁹ This means that it is beneficial for those providing ethics consultation to be skilled in communication and conflict resolution abilities.

According to a paper discussing data from the first 5 years' experience of a Hospital Ethics Committee from a Pakistani institution, the majority of consults were related to end of life issues, lack of financial resources to carry on treatment, familial conflicts, social and cultural clashes and issues relating to patient autonomy.²⁰

Research Ethics

The development of research ethics as a distinct area of interest within bioethics can be linked to historical events in which human subjects were exploited for scientific purposes. Experimentation is essential for scientific progress, and experimentation on human participants is imperative for medical science to progress. However, the history of human experimentation is replete with examples when participants were exploited, deceived and harmed in the process of such experimentation. Awareness of such abuse and attempts to keep it in check is also evident from historic times, reflecting the concern for the welfare of the human subjects.²¹

Early Attempts at Ethical Regulation of Research

Attempts at regulating human subject research is not a recent phenomenon and the following examples will illustrate that attempts at safeguarding the interests of human subjects involved in medical research date back a long time. As far back as 1803, Thomas Percival, an English physician and philosopher was credited with developing a Code of Medical Ethics which stated, among other things ‘and new methods of surgical treatment should be devised but should be scrupulously and conscientiously governed by sound reason, just analogy, or well-authenticated facts previous consultation of the physicians or surgeons to the nature of the case.’ He went on to state that such experimentation ‘must have good methods and competent investigators’.

In 1833, William Beaumont developed the oldest known American document dealing with research. He acknowledged in this document that experimentation is needed and that information cannot be otherwise obtained, but stressed that the investigator must be conscientious and responsible and follow a sound methodological approach. He also emphasized the importance of voluntary consent for including participants in research.

In 1865 a French physiologist Claude Bernard published ‘An Introduction to the Study of Human Experimentation’ in which he recommended: ‘Never perform an experiment that might be harmful to the patient even though highly advantageous to science or the health of others’.

Two other important landmark documents regulating human experimentations both came from pre World War II Germany. The 1900 Prussian Directive prohibited experiments in minors and those not fully competent and required unequivocal consent after explanation of the experiment and possible adverse consequences from participants. The Reich Health Council Regulations of 1931 presented 14 points which required informed consent from participants as a necessity, a requirement for risk which included a benefit analysis, the need for a justification for studying vulnerable populations and the necessity for written records of the experiment.

This indicates that enough concern was already there at the turn of the twentieth century for safeguarding the rights of human subject in research. However, this concern and the guidance documents already in existence did not prevent great atrocities to take place on human subjects, the worst of which took place in WWII and post war years.²²

Certain examples of human subject exploitation merit detailed mention in this text since they were instrumental in the formulation of future corrective strategies.

Nuremberg Tribunal

Nazi experimenters performed most inhuman medical experiments on their captives during the Second World War. They did so with the justification that they were furthering the cause of science and their subjects were, according to their reckoning, lesser humans and therefore expendable at the altar of science. These experiments included locking people in decompression chambers to see at what pressure people lost consciousness and at what level they actually died. In other experiments they would submerge limbs of prisoners and even their entire bodies in ice cold water to see when frostbite set in and how long it took for the person to freeze to death. No permission was obviously sought from the helpless captives for including them in such research projects, despite the availability of documents governing human experimentation, mentioned above.

After the allies won the war, twelve war crimes tribunals were set up in the city of Nuremberg, one of which, called the Doctors Trial, dealt exclusively with human experimentation.²³ This tribunal consisted of American judges and out of the 23 defendants, 7 were acquitted, while 7 received death sentences and the remainder were served sentences ranging from 10 years to life.²⁴

As a direct consequence of the Doctors Trials in 1947, a 10 point section ‘Permissible Human Experimentation’ was developed which went on to become the Nuremberg Code. This code stressed the requirement for a voluntary consent of the human subject as an absolute essential for their inclusion in any human experimentation. Although never included in the legal framework either in the US or Germany, the Nuremberg Code has had a major impact on the development of subsequent regulatory documents in human subject research.

Unit 731

Although the Nazi atrocities during WWII were swiftly noted and brought to trial following the war, similar deplorable experimentation taking place during the same time period remained hidden for decades. During the Second Sino-Japanese War (1937–1945) and World War II, the occupying Japanese Imperial Army developed what was known as Unit 731, a covert biological and chemical warfare centre in the region of Manchuria, North Eastern China. The main objective of this unit was to develop biological and chemical weapons and the army scientists at the unit used their Chinese captives to conduct horrific experiments, including bleeding them to death, infecting prisoners deliberately with infectious diseases to study disease progression, and testing live ammunition like bullets and grenades on living human captives. These experiments did not come to light because immediately after the war was won by the American allies, the matter was hushed up, and the scientists given protective immunity in exchange for the scientific data which America considered useful for its own purposes. Many of the Japanese experimenters found their way into the American academia and drug industry despite their past. This is in sharp contrast to what happened to the Nazi German doctors who received imprisonment or death sentences for similar experimentation. It is only as recent as in 2002 that the Japanese courts have acknowledged the occurrence of Unit 731 but the government is yet to acknowledge these events.^{25,26}

Henry Beecher’s Expose

Stories of inhumane experimentation in the name of science unfortunately are not confined to times of conflict. There are many experiments that have gone on in peace times also. In June 1966, Henry Beecher, an anesthesiologist working at an American hospital, published an article in the New England Journal of Medicine in which he described 22 studies on human subjects that were in clear breach of well established ethical norms of the day. Here are three examples from his list.²⁷

Radiation experiments were conducted by the US government from 1944 going on till the 1980s to see the effects of radiation on normal humans, as part of the US nuclear program. No informed consent was obtained, and in fact deceptive means were used on parents to lure children by offers of beach trips. There was obviously no possible benefit of participation and many participants developed radiation sickness and cancers as a result of this exposure to radiation.

In the Willowbrook Hepatitis Study, which started in 1955 and continued for 15 years, the objective was to gain an understanding of the natural history of infectious hepatitis and to test the effects of gamma globulin in preventing the disease. The Willowbrook State School was meant for children with mental disabilities and there was a great demand for admissions. Coercion was used to obtain informed consent from the parents since admission was granted to only those children whose parents agreed to let their child be part of the experiment. The subjects, all children, were deliberately infected with the hepatitis virus; early subjects were fed extracts of stools from infected individuals whereas later subjects received injections of more purified virus preparations, resulting in severe cases of hepatitis in the unsuspecting subjects. Investigators defended the deliberate exposure of these children to disease by saying that the vast majority of them acquired the infection anyway while at Willowbrook, and perhaps it would be better for them to be infected under carefully controlled research conditions.

In 1962 the Jewish Chronic Disease Hospital Study was conducted to generate information on the nature of the human transplant rejection process. Chronically ill patients who did not have cancer were injected with live human cancer cells to see if cancer cells were implanted or not. The physicians did not inform the patients as to what they were doing. The physicians' justified their actions by saying that they did not want to scare the patients and they thought the cells would be rejected anyway.

These were just a few of the examples described in this article. As a direct consequence of Beecher's article, a great hue and cry was raised not only in the medical and scientific community but also in the general public against such exploitative scientific studies.

Tuskegee Syphilis Study

Tuskegee study has left a lasting impact on research ethics. In 1932, the US Public Health Service initiated a study called the 'Tuskegee Study of Untreated Syphilis in the Negro Male'. The objectives of the study were to record the natural, untreated progression of syphilis, a disease with no established cure at the time of commencement of the study. The study recruited 600 black men and was conducted without the subjects' informed consent. Researchers in fact deceived the men by saying that they were being treated for 'bad blood,' a local term used to describe several ailments, including syphilis, anaemia, and fatigue. In truth, they did not receive any treatment needed to cure their illness. Even when penicillin became the drug of choice for treating syphilis in 1947, researchers did not offer it to the subjects. In fact, they made sure that study participants were denied access to penicillin from any other source accessible to them. Furthermore, no participants had the option of quitting the study. The study came to light only in July 1972, through a news report which prompted a public outcry that led to a government investigation. The advisory panel constituted as a result concluded that the Tuskegee Study was 'ethically unjustified'-- the knowledge gained was sparse when compared with the risks the study posed for its subjects, and in October 1972 the panel advised termination of the study at once. In 1997 President Clinton formally apologized to the victims of the infamous Tuskegee Study.²⁸

Guatemala Experiments

In 2005 yet another US government led experiment came to light. This was the syphilis experiments funded by the National Institutes of Health and conducted in Guatemala in the mid 1940s. In order to note the effect of penicillin in the prevention and treatment of venereal diseases, researchers purposefully infected soldiers, commercial sex workers, prisoners and patients with syphilis and other sexually transmitted diseases, without their informed consent. This was in contrast to the Tuskegee syphilis study where the objective of the study was to see the natural untreated progression of the disease. Interestingly, the lead scientist in this study was involved in the Tuskegee trial also. About 1500 people were recruited for experimentation, of which at least 83 died. The Surgeon General at that time acknowledged that such experiments could not have been carried out within the US. In October 2010, the US President formally apologized to Guatemala for conducting these experiments.²⁹

Guidelines for Ethical Research

The potential risk to participants from involvement in scientific research is clearly evident in the examples cited. In addition to the Nuremberg Code, there are several other contemporary documents which have been created to minimize such exploitation of research participants. Three of them are briefly described below.

The World Medical Association Declaration of Helsinki called 'Ethical Principles for Medical Research Involving Human Subjects' was adopted by the 18th. World Medical Association (WMA) General Assembly, Helsinki, Finland in June 1964. It has subsequently undergone several revisions and amendments with the latest update in 2008. At the time of writing of this chapter, the WMA had called for a public consultation on the Declaration to bring about a fresh revision. The Declaration is addressed primarily toward physician researchers, but the WMA encourages all researchers involving human

subjects to adopt these principles. These guidelines are the first to suggest independent ethical review of all research involving human subjects.³⁰

In 1979 the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research developed the Belmont Report of 1979. This document still plays an important role in human subject protection in the US. Central in this guideline are three principles of respect for persons, beneficence, and justice.³¹

In 1982 the Council for International Organizations of Medical Sciences (CIOMS) developed 'International Ethical Guidelines for Biomedical Research Involving Human Subjects'. These guidelines have been updated twice in 1993 and 2002. In addition to other areas, the CIOMS guidelines stress on the need for ethical justification and scientific validity of research, the various facets of informed consent and vulnerability of individuals including women and marginalized groups. These guidelines specifically address the ethical issues that emerge in research involving developing countries' participants. They also address issues regarding burdens and benefits of research, confidentiality of data, compensation for injury and the obligations of sponsors to provide health-care services.³²

In addition to these guidelines there are several regional documents from different countries that deal with human subject research including social sciences research.

Ethical Review Process

The realization for the need for ethical oversight of human subject research has gradually developed over the past two or three decades. It has now become mandatory to have an ethical analysis of all research involving human participation. This is undertaken by Institutional Review Boards (IRBs) also called Ethical Review Committees. Funding agencies which provide money for major research projects now require mandatory ethical reviews before they commit money for research. Similarly, reputable journals will not publish research articles until they are provided with information regarding ethical review. Also accreditation and examination institutions like the College of Physicians and Surgeons of Pakistan require ethical review before they accept thesis and dissertations based on human subject research. It is for this reason that institutions across the world are keen on developing IRBs.

In Pakistan also, the need to create IRBs was felt by premier institutions because of review requirements mandated by funding agencies, journals and foreign collaborators. The last few years have seen a proliferation of these bodies across Pakistan. In 2011 the Pakistan Health Research Council (PHRC) conducted a study of IRBs in medical institutions across Pakistan, and reported the findings at a national workshop held in November 2011, at the Centre of Biomedical Ethics and Culture, SIUT. According to the findings, of the 58 institutions that participated in the mailed-in survey, 48 had functioning IRBs. The majority of them (67% in the public sector and 44% in the private sector) were of less than 5 years standing. The study also revealed that 57% of the public sector IRBs and 41% of the private sector boards offered no training in research ethics to their members.³³ This casts a shadow on the caliber of some of these committees.

An IRB generally consists of members from different departments of the institution, including physicians, nurses, hospital administrators, a lay member from the public, occasionally a person with a legal background and often also a religious scholar. In order for the IRB to work effectively, these have to be independent, and manned by upright individuals who are held in high esteem at their institution and by the community. It is beneficial for the IRB to have members specifically trained in ethical review. This can be through formal degree programs or even short courses and workshops. After review, the IRB can either allow the research to commence, seek amendments to bring the project in compliance with ethical requirements, or in rare instances, reject a protocol found to be entirely unethical and not amenable to modifications.

The IRB review has several considerations. One of the main focuses of the review is to ensure that human subjects are not exploited as research participants. The requirement for an informed and understood consent which has been given willingly and without coercion is paramount in recruiting participants. This becomes even more critical in male dominated and hierarchal societies like Pakistan where male members of the family and elders consider their opinions to be final, over and above the woman who is the actual research participant.³⁴ In addition to looking at the consent document, the IRB will also examine the process through which it was obtained, keeping in mind relevant cultural sensitivities. Any compensation being offered for participation will also be critically examined by the IRB, to rule out any element of inducement introduced by a reward for participation that is too good for the participant to refuse, therefore clouding his or her judgment.

There are several other considerations that the IRB examines in research proposals. These include balancing of risks of participation versus perceived benefits for research subjects, and the criteria whereby the subjects and their community was chosen for conducting research. This is particularly important in research conducted in developing countries like Pakistan where ignorance, illiteracy, lack of access to healthcare and poor regulatory processes all contribute towards an ease of subject recruitment, even for high risk research. The IRB will therefore look very closely at the issue as to why a developed country researcher or organization is choosing to locate their research in an impoverished and underdeveloped community. Another aspect that the IRB will assess is the access to benefits of any potential products of the research, if and when they become available, including the issue of affordability of a product developed as a result of the research by the local population on whom it was researched.

Some research projects can be potentially stigmatizing for the participants and the community because of the information that they may bring to light. For instance, as a result of a study on the incidence of smoking among girl students at high school level, just the fact that girls of one particular school were found to be smokers in large numbers as compared to another school could be stigmatizing for the school and may have repercussions for the school and its pupils. IRBs assess any such possibilities in their review and ask for measures to avoid such consequences.

Another area that the IRB looks at carefully is conflict of interest (COI). A conflict of interest is ‘a set of conditions in which professional judgment concerning a primary interest (such as patient’s welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)’.³⁵ COIs can be financial or non-financial. For instance, the primary interest of the researcher, the integrity of his research, may be in conflict with secondary interests such as monetary gains, papers in journals or academic advancement resulting from the research.

An interesting finding of the PHRC study quoted above revealed that over 80% of the IRBs were headed by the institutional head. There is inherent COI in this arrangement since the institutional head will have a conflict between the requirements of an ethical review versus the potential benefit of funding that the approval will bring for the institution he or she heads. This also underlines the need for a central regulatory authority which sets guidelines for the proper functioning of these committees, and provides an accreditation and regulatory mechanism so that these mushrooming IRBs are worthwhile.

Public Health Ethics

Public Health is the organized response by society to protect and promote health, and to prevent illness, injury and disability. The focus of Public Health initiatives is towards the promotion and protection of the health of the public in general, as opposed to individually focused efforts in a classic patient-physician relationship. There is overall benefit as a result of public health policies developed by organizations such as the World Health Organization, Centres for Disease Control and Prevention (CDC), the US Food and Drug Administration (FDA) and numerous other national and international organizations.

The field of Public Health in Pakistan has not received the attention it merits. In fact, medical colleges still use the antiquated title of 'Community Medicine' for departments that deal with public health issues. High class training opportunities in the field are also scarce in Pakistan. Whereas there are plenty of world class programs offering training in several cutting edge basic sciences and clinical fields, opportunities are only just emerging for public health training in this country.

Since the global focus of public health is for collective good rather than on individual welfare, the field leads to ethical concerns in several areas, some of which are discussed below.³⁶

Coercive Measures

One major area of debate in public health ethics is the conflict between individual rights versus public good. For instance, instead of simply focusing his efforts on the medical care of the one passenger with fever disembarking from a flight inbound from a country with a SARS epidemic, the public health physician will be looking towards safeguarding the welfare of the entire community. Therefore, infringing the liberty of the febrile passenger and quarantining him from the public will be a justifiable act until he no longer remains a threat to the community. Public health measures are often based on the assumption that they are the right thing to do. The quarantined passenger may just have had the common cold, his liberty curtailed unnecessarily on the mere suspicion of SARS, yet it would be ethically and legally justified.

A major ethical concern with public health measures is that they are often coercive. Such coercive measures are ethically justified under the doctrine of the 'Harm Principle' enunciated by John Stewart Mill in 1869 in his essay 'On liberty'.³⁷ According to this principle, the actions of individuals should only be limited to prevent harm to other individuals. Thus quarantine, isolation and similar such measures are justified using this argument, and the greater good of the public is deemed to override the principle of individual rights.³⁸ The same argument has been invoked to justify measures like the compulsory use of seat belts in cars and helmets for motor cycle riders. Although it may be within the individuals rights to indulge in risky behaviour, injuries sustained as a result of ignoring proven safety measures lead to utilization of emergency hospital beds as well as public resources, thereby justifying enforced compliance.

Similarly, the banning of cigarette smoking in certain situations is justified on the same principle. Although the individual is exercising his civil liberty by indulging in a risky behaviour himself, second hand smoke is known to cause injury to those around him. It is therefore justified to ban smoking where it can harm others like in all closed spaces and public places.

Implementation Issues

Public health measures necessarily require governmental action for implementation. If they are to succeed, they need political as well as community commitment, as an example will shortly illustrate. For instance, quarantining the passenger on the mere suspicion of SARS (even if based on an erroneous assessment) is done to prevent public harm. The individual must realize that this is not a punitive measure against him, and is undertaken reluctantly by authorities and for the safety of the community. A vaccination program such as the expanded program of immunization can only succeed if the public buys in and agrees to have their children vaccinated, accepting the small but potential harm that can also come from such interventions; like fever, local pain and possibly illness. The potential of widespread harm if the public or even a segment of the public refuses to comply is evident by the example of resistance to the polio vaccination program in certain areas of Pakistan. That focus of disease can potentially become a global threat.³⁹

Long Term Benefits

Moneys pledged for public health measures today often yield results only in the long term, perhaps even for future generations, as in lowering rates of communicable diseases, eradication of certain diseases or

the prevention of epidemics. Monetary investments are therefore made on assumptions that the public health policies will actually work, thereby requiring serious commitment from the government. With the finite resources available to governments, the issue of justice of healthcare resource allocation comes up, weighing moneys committed for treatment of current patients versus preventing diseases for an unidentifiable subgroup of population at an undefined time in future. Public health commitment requires vision in addition to political will.

Another interesting debate revolves around the definition of public. Who exactly is the public that Public Health addresses? Concerns regarding public health naturally cross borders since diseases are not limited by national borders. A parallel can be drawn here between transnational public health determinants and environmental threats both cross national borders. For instance, disasters in one country can put to risk the welfare of populations in a neighboring country, the Chernobyl nuclear meltdown in April 1986, and the Fukushima Daiichi nuclear disaster in March 2011, just to mention two. An outbreak of a deadly virus in one corner of the world has potential danger for the entire globe. The threat of polio pockets in Pakistan threatens the entire world. Should then public health measures stop at borders or should they cross borders in hot pursuit. It also raises the question whether punitive measures are justifiable for noncompliance to known public health practices. For instance, other nations can potentially enforce travel sanctions by imposing visa restrictions on Pakistani citizens for failure to comply with global standards by not enforcing adequate measures to eradicate polio.

Organizations such as the World Health Organization (WHO) play their role as a global enforcer. However, WHO acts through individual governments and 194 countries are signatories of the International Health Regulations to enforce public health security globally.⁴⁰ It is being increasingly recognized that public health deals with global health, and university departments are now actually named as such.

Maldistribution of Benefits

Another ethical area of concern is an inherent unfairness in distributing the burden of certain measures on one segment of the population to benefit another. In the area of taxation, governments tax the rich and not the poor, with the proviso that facilities provided from the taxed incomes will be distributed equitably to all segments of the society. Cigarettes are taxed heavily, making the risk takers pay more for their hazardous habit.

In Japan, flu vaccination had once been made mandatory for school children so that the elderly may be protected from exposure, since they are more likely to suffer greater morbidity of the seasonal outbreak.⁴¹ An ethical justification is necessary for such an intervention which is designed on one segment of the population to benefit another. In this case of course, the children were also benefiting from protection. However, some would argue that healthy children would actually not require to be given seasonal flu protection in the first place.

Ethical Challenges in Organ Transplantation

Challenges that have been under debate ever since it became possible to replace failed organs in desperately sick individuals with working organs from either healthy, living donors or recently deceased ones. Ethical issues around organ transplantation are heavily influenced by religious, cultural and social values when the process of organ donation is considered, whether from the living or the deceased. In the following passage, some of the ethical debates specifically around kidney donation will be highlighted since kidney transplantation programs are the only ones established in Pakistan at the moment.

Living Kidney Donations

Surgery for organ donation is a unique operation. There is no other example of a healthy person willingly undergoing a surgical procedure that has no conceivable medical benefit for himself or herself, and readily

accepting the inevitable pain and also the small but established short and long term risks associated with nephrectomy. Yet kidneys from living donors form a major share of transplanted organs in Pakistan. Since kidneys are paired organs, and a healthy donor can be expected to have a normal lifespan even after donating one kidney, taking a kidney for transplantation from a willing adult donor raises no ethical concerns. The motivation of people to donate an organ for the sake of restoring to health a seriously sick relative or spouse is quite understandable. True altruism, in which a person is willing to donate a kidney to a complete stranger to help him or her recover is also possible but is probably much less common.

More common, especially in the Pakistani context, at least up till a few years ago was complete strangers 'willingly' donating their organs to total strangers, often foreigners. This was brought about by a well-established commercial process whereby the poorest of the poor were coerced to sell their kidneys in order to buy their way out of debt. The recipients were always affluent people, often from other countries. In this process of buying and selling of kidneys, the real benefit was in the form of money made by middlemen, hospitals and doctors. Studies have shown that the organ vendor, the poor peasant who sold his or her kidney, would still remain in debt and would be left financially as well as medically worse off than before.^{42,43} This problem of organ trade grew to such a level in the country that at the turn of the century Pakistan was regarded as the 'kidney bazaar' of the world with private hospitals in Punjab catering specifically to this business. Not only did this bring a bad name to the country, this practice was also causing a major health issue for the 'donors' who were selling their kidneys since there was no follow up offered by these commercial transplant centres.

The struggle to bring the menace of organ trade to an end in Pakistan spans more than two decades. This effort was spearheaded by the SIUT, aided by national nephrology and urology societies, the media and members of the general public. It was in response to a suo moto notice taken by the Supreme Court of Pakistan that an ordinance was finally promulgated in 2007 banning organ trade, criminalizing transplantation of organs from Pakistanis to foreigners, and supporting living, related donations. The ordinance, called 'Transplantation of Organs and Tissue Ordinance 2007' also ordered the creation of a regulatory and oversight organization called the Human Organ and Transplantation Authority (HOTA).⁴⁴ The ordinance was unanimously ratified by the parliament to become law in 2010. After the 18th constitutional amendment, the provinces have been directed to establish such committees and take over the role of HOTA.

Deceased Organ Donation

In major transplant centres across the world, it is the deceased donor programs that are being developed to meet the ever increasing needs for organ transplantation. This is because the deceased is obviously not going to be harmed by the removal of organ/s and even in death, can help restore the life of a severely sick person.

In Pakistan however, to date only 4 Pakistanis have been deceased donors. This is primarily because of lack of awareness among the public as well as among medical professionals about the various aspects of deceased organ donation. Although there are numerous fatawas from ulema belonging to different Islamic schools of thought declaring deceased organ donation permissible in order to save the life of another human being, according to a study conducted by the author, ambiguity still remains in the minds of the general public.⁴⁵ This study also highlighted many social and cultural aspects of deceased organ donation which need to be addressed before any such program can be started in Pakistan to contribute meaningfully towards organ transplantation activity. For instance, even if an individual has willed his or her organs to be donated after death, this study showed that the family can intervene after the death and refuse to honor this pledge. This is by no means unique to the Pakistani context, but a formal role for the family will have to be considered while getting pledges for deceased organ donations so that the possibility of a veto from the family after death can be minimized.

There are only certain kinds of deaths that can be followed by organ retrieval. The best results have been obtained if organs are retrieved while still being perfused with oxygenated blood. This can only happen if the heart is still beating after death has been declared. This became possible in the mid 1970s of the concept of Brain Death as opposed to the classical concept of Cardiopulmonary Death. In the former, death is declared even as the heart keeps beating, based on irreversible brain injury thus making organ retrieval possible from a dead person with an intact circulation. In the latter case, circulation obviously ceases and the window of organ retrieval is very limited and the resulting transplant not as successful. Brain death is now widely accepted as a mode of death, but in societies such as ours where awareness is still limited, it is difficult for families to consider a loved one with a beating heart as being dead.

There are several other aspects of deceased donations that raise difficult ethical questions, but are beyond the scope of this chapter.

Ethical Issues in Physician Interaction with the Pharmaceutical Industry

Crucial role in drug and device development and provide the armamentarium to physicians to combat disease. However, a growing area of ethical concern all over the world is the increasing influence of the industry on the prescribing practice of physicians. This has been extensively documented not only in scientific journals but also in the lay press.^{46,47,48} Like any industry, the pharmaceutical as well as the device industry (making various devices used and implanted in patients) looks to increase its sales, which is a legitimate objective. However, one of the main ways of enhancing sales is to have physicians favorably prescribe their products rather than of a competitor. And with so many similar and equally efficacious medicines and devices available, it is here that the influence of a particular pharmaceutical company on the physicians matters critically.

Any association between physicians and pharmaceutical companies or medical device manufacturers has the potential of leading to conflict of interest.⁴⁹ The primary interest of a treating physician should be the welfare of his patient, which means prescribing the best, most efficacious and economical medicine that he thinks suits his patient's needs. However, when the physician has been the beneficiary, for instance, of an all expense paid trip to a resort location abroad sponsored by a particular drug company, a sense of obligation towards the benefactor is bound to be there, along with the hope of future similar opportunities. Here the secondary interests of the physician, (personal gains in this example), have every likelihood of influencing him to prescribe the products of that particular company.

Attempts at influence on health professionals by drug firms starts early and very subtly. Practically every physician and even most medical students will be seen with at least one item on their person bearing the logo of a drug firm or their product, be it a pen, a prescription pad, a mug, tissue box, a stethoscope or a multitude of other giveaways. These are subtle ways of initiating a subliminal influence which only grows with time.⁵⁰

The same sense of obligation cultivated by the industry is also there when the favors extracted from the company are not even personal but ostensibly for the welfare of the patients. The handing out of sample packs of medicines free of cost to prescribing physicians is also not entirely without strings attached. Any free samples of medicines given to a patient by the doctor practically guarantees that the patient will buy that same medicine after he or she runs out of the 3 or 4 tablets in the pack, and with the pricing formulas worked out by the industry, the cost of the 'free' samples is extracted several times over by the company from the patient it professed to help.⁵¹

The intent to influence physicians by the industry is of course strongly denied by the industry. In fact their own professional codes and guidelines clearly state that no such attempt should be made. Also, equally vehement in denying any influence are physicians themselves. However there are enough studies now indicating unequivocally that favors like gifts of any kind can and do influence the recipient

physicians.^{52,53} The greater the value of the gift, the more obligation on the physician to reciprocate, and the only way to reciprocate is to write more prescriptions of products made by the company whose generosity the physician has been enjoying.

A critical look at the influence of the industry on medical care has become all the more important in recent years since traditionally, a major part of funding for continuing professional education events came mainly from the industry. This is however changing in the developed world, because of the realization of the industry influence that comes hand in hand with the money.⁵⁴ Additionally, funding for clinical research is also provided mainly by the industry, often enabling the industry to choose the diseases on which it wishes to promote research, and which it wishes to ignore. Also, a drug that a pharmaceutical company develops is typically patented by it and it reaps profits from its subsequent sales, often through pricing regimens beyond the reach of the common man. A recent ruling of the Indian Supreme Court to deny a giant multinational company of patenting an anti cancer drug that it had developed, can go a long way in bringing prices of critical drugs down and within the range of affordability of poor patients.⁵⁵ As is obvious by these two examples, ways can be found to control the commercial influence of drug firms on how medical research and medical care is carried out. The same kind of proactive approach needs to be instituted in Pakistan where the industry still continues to wield a lot of influence on continuing medical education events as is evident by the advertising inside and outside medical conferences across the country.

There has been a worldwide recognition of these inherent COIs as a result of these interactions. In the US, the Congress has recently legislated to curtail these influences by enacting the Sunshine Law whereby all gifts and grants to medical professionals, bodies and organizations have to be declared in a publicly accessible domain such as a website that anyone can reach.⁵⁶ Other initiatives include the American Medical Association Code of Ethics.⁵⁷ Similar moves are afoot in other parts of the world and aggressive pharmaceutical marketing is being met by equally aggressive counter measures.⁵⁸

Pakistani medical institutions and physicians, as in the rest of the world, rely heavily on pharmaceutical funding for a variety of their activities. Such dependence on industry sponsorship has steadily blurred the borders between academia and the industry, a situation that suits the industry. Concerns are however now increasingly being raised from different quarters in the country.⁵⁹ Ethical guidelines have been developed and proposed, both from the governmental level through the National Bioethics Committee as well as from within the medical community.^{60,61} While acknowledging the importance of the pharmaceutical and device industries in modern day healthcare, it is also essential to sensitize the young physicians about the ethical concerns that can emerge from unregulated interaction with the industry.

Emerging Ethical Challenges

Newer and more challenging ethical issues have emerged resulting from medical and technological advancements and environmental concerns. For instance, recently scientists have been able to create the very first entirely man made synthetic one celled organism which also has the capacity to reproduce.⁶² This scientific milestone has opened the floodgates to a variety of challenging ethical issues about the human capability of creating life, and where to draw the line. Should they stop at the level of single celled organisms, (for instance bacteria designed to eat up oil slicks in oceans), or viruses (to combat other deadly viruses), or perhaps even multicell organisms? Should limits be set to human innovation and inventiveness? Also, can scientists or a company have ownership of the life that they create, as in patenting life forms?

Alongside these technological leaps, bioethical debates have also tried to keep pace, attempting to address these questions. Rapid globalization has ensured that new advancements in industrialized countries rapidly make their way to developing countries as well. Some of the issues discussed in the next section may seem irrelevant to the socio-cultural and religious context of Pakistan, but a student of bioethics should be aware

of the global debates that are taking place on such issues as well. This section will give an overview of some of these emerging challenges.

Reproductive Technologies

Recent advances and easy availability of reproductive technologies have been effective in treating a variety of causes of infertility. In vitro fertilization (IVF) performed using gametes of a married couple is available in Pakistan and has religious and legal sanction. However, with biotechnological advancements, options offered to circumvent infertility have rapidly pushed the ethical boundaries in many parts of the world and the entire concept of the 'normal' family now stands challenged. While one mother and one father are still regarded in much of the world as constituting the 'parents' of a baby, it is now technically possible for a baby to have five parents simultaneously: a sperm donor, an egg donor, a surrogate mother (who carries the baby in her womb for the gestation period), and the two contracting individuals (who may or may not be of different sexes) who have hired the three for their services.⁶³ With these technologies, it is also possible for a single person to 'have a baby' as it is for same sex couples. Similarly, it is now also possible to have three genetically related parents of an embryo. Sperm from one person and ova from two women have recently been used, taking the nuclear DNA of one egg and the mitochondrial DNA of another to eliminate mitochondrial DNA based diseased genes from the main donor, making an embryo that has three genetically linked parents.⁶⁴

Ethical, legal and moral debates have revolved around trying to define parenthood in such circumstances. For instance, a challenging situation would emerge in the case if, after initiating the whole process, the contracting couple decides to separate and none of them wants the baby which is in the gestational process. Another important issue that arises in such situations is whether the baby born out of such a combination, has a right to know his or her biological parents. In several developed nations where sperm donation for insemination is practiced, donors have to be identifiable and can no longer remain anonymous in case any future offspring wishes to know of their biological roots.⁶⁵

The other issues that come up are those of exploitation of the poor by those who can afford to buy their way out of infertility. Although the surrogate or the ovum donor may have provided well documented consent, however they are driven to do so only out of sheer poverty and the lack of any other choices. It is always the poor women from developing countries who sell their ova and rent their uterus to produce babies for rich, often foreign couples. These are not harmless pursuits, and involve serious stresses on the woman's body either for hyperovulation for ovum donation or when she carries someone else's baby for 9 months as a surrogate mother.⁶⁶ Although this is not an issue that has surfaced in Pakistan, but it is already a major concern in India where, because of the money it brings, surrogacy is legal.

Genomics and Its Challenges

There has been rapid progress in genomics in recent years after the unraveling of the human genome. Anyone can have their genome 'checked' for a fee by simply sending a little bit of sputum to a lab.⁶⁷ The cost of whole genome sequence has come down from millions of dollars and is projected to cost as little as routine medical tests in the near future. With such easy and cheap access to genetic information, the concept of privacy is being challenged. Potentially any researcher could find out a host of things about individual, information that the person may not wish to share, or even to know himself. The increasing availability of such information can also lead to ethical issues when insurance companies or employers may wish to access information about particular genetic traits. This could lead to a whole new kind of discrimination. Each individual has a unique genome, and may consent for information to be extracted for analysis. However, the revealed information can go beyond the individual whose DNA was analysed, since genetic traits are shared within families, clans and tribes. The recent case of the Havasupai tribe in USA revealed how this can cause major ethical issues at the community level. This tribe lives at the bottom of the Grand Canyon in Arizona, USA. Biological samples collected by researchers ostensibly to look at some medical issues of the tribe were used, without consent, for genetic tests on the basis of which

certain inferences were drawn relating to the origin of the tribe and its descendants. These findings were in direct conflict with long held beliefs of the tribe and offended members of this small community. This resulted in a lawsuit against the institution and subsequently out of court payment of heavy compensation to the wronged tribe members. This case is now considered a landmark in the ongoing debate on genetic testing and what to do with the information.⁶⁸

These issues have been addressed by a US Presidential Commission on Bioethics which has come up with a list of recommendations.⁶⁹ As costs plummet, and tests get easier to perform, their availability in Pakistani populations is a certainty which is why this debate is of relevance to Pakistan as much as it is to developed countries.

Another set of issues stemming from genetic testing relates to the unveiling of information that may be difficult to process, comprehend and act upon. For instance, through genetic testing of a drop of blood from a newborn baby, it is becoming possible to predict to varying degrees of certainty, the occurrence of diseases in future life. This raises the question whether it is ethically permissible to make these predictions by performing such tests, especially so when little may be offered in the way of avoiding the predicted disease. Conversely, if such tests are available, another issue would be whether it is ethical not to offer them to the parents of the baby, so as to enable them to plan and even potentially avoid or delay the anticipated outcome. Along the same lines, should a 16 year old girl be told that, based on a new genetic test, she has an 80% probability (not certainty) of having lethal breast cancer in either of her breasts and the only certain avoidance is elective bilateral mastectomy? The entire field of genetic counselling has emerged in the wake of such advancements and such tests are done only after much deliberation. Also, even if the genes predict a certain outcome, there is a huge impact on the ultimate disease expression by environmental factors. In such a situation, handling genetic information becomes even more complicated. These issues have been addressed by a US Presidential Commission on Bioethics which has come up with a list of recommendations.⁶⁹ As costs plummet, and tests get easier to perform, their availability in Pakistani populations is a certainty which is why this debate is of relevance to Pakistan as much as it is to developed countries.

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Even before birth, it is now possible to study the genetic makeup of an embryo employing preimplantation genetic diagnostic techniques. This opens the possibility of treating diagnosed and treatable disorders at the embryonic stage, and then implanting the most desirable embryo for development into a baby. This sounds laudable so long as medical disorders are being diagnosed and corrected; however this also opens the way for designer babies, where parents may wish to select or modify embryos so that their child has a certain complexion, colour of eyes, built and so on, in addition to a more desirable IQ level.⁷⁰

Biobanks and Stored Samples

Another emerging concern revolves around the availability of huge amounts of stored samples in pathological labs. These samples are essentially left over after the performance and reporting of pathological tests for which they were obtained, and stored in biobanks. These samples can be used for a variety of genetic testing at present and can also be stored indefinitely for future research. Although, this makes scientific sense, especially because the individual to whom the sample belongs has no use for it anymore, but the debate is whether it is ethical to use someone's cells and genetic materials for research which may reveal facts that the person may not wish revealed. Is informed consent needed or even practically possible in such research? How can one take informed consent when research is not even planned and may take place years into the future using methods not even in existence today? Several guidelines have been developed, and while none are accepted universally, but it indicates the level of discomfort with research on stored samples.⁷¹

Stem Cell Research and Therapy

The possibilities of using pluripotent stem cells to regenerate dead cells, say in the heart after a myocardial infarction, or neuronal cells in patients with Alzheimer's disease or spinal injury are very attractive, and scientists are making serious efforts of converting the present abstract hype to tangible hope. The essential requirement fueling this research is the availability of stem cells of which human embryos form the most readily accessible source. This has led to the major ethical debate whether it is permissible to create and then destroy embryos for obtaining their cells. Is a cluster of a few cells 'life' and if so, should it be accorded the respect one would a mature fetus? If not, then where is the point where life begins and it therefore, becomes incumbent to accord it the due respect of a living being? It was as a result of such debates that there was a moratorium on using embryos for stem cell research in the US, using government money. It was considered permissible by some to use leftover embryos from IVF, destined for destruction, to be used in research with the permission of the parents. With the advent of better technologies however, adult sources of stem cells have also emerged, thereby reducing the necessity of relying on embryonic tissue. In fact the Nobel Prize in Medicine for 2012 was shared by a Japanese and a British scientist for converting adult cells into pluripotent stem cells. This achievement will reduce the ethical issues haunting this promising field.

Environmental Concerns

It is only recently that awareness about environmental degradation is beginning to be discussed by the mainstream public. With only a finite amount of natural resources, and ever increasing demands on them by exponentially growing populations, the environment has become everyone's concern. Ethical debates abound in this area as well.

One particular area of debate is in the manipulation of nature for enhancing productivity. For instance, is it ethically permissible to manipulate naturally occurring substances like seeds to enhance their per acre yield? Such genetic manipulation of seeds has been used to enhance the vitamin and mineral content of crops in an effort to combat malnutrition or specific deficiencies. However, there is also a heated debate on the engineering of such genetically modified crops to become seedless, thereby compelling the farmers to become dependent on commercial entities for their seeds. Since the genetically modified seeds have been produced by a biotech firm, the seeds and their production is owned and patented by that firm, which will sell them like any product to the farmers. This raises the issue of patenting naturally arising substances. A prime example of such a patent is that for basmati rice. In 1997 a US company attempted to patent basmati rice which led to an outrage and even a diplomatic battle against it.⁷² The ethical concerns on private ownership of a naturally occurring substance can be easily appreciated.

Conclusion

Although concepts of bioethics have gradually made their way into the Pakistani academia, despite the sudden increase in bioethics trained personnel, the country still lags behind in incorporating ethical norms and standards within clinical practices, research and education.

While the rest of the world debates emerging ethical issues, this discourse is entirely missing in bioethics circles within Pakistan, both in the lay press as well as in scientific meetings. Although biobanks are making their appearance in Pakistan, there is hardly any debate on the ethical guidelines to govern them. We have already seen our share of stem cell therapy scams in the country, yet this topic is not discussed in conferences researchers attend.⁷³ While the world moves towards debating the ethical issues in nanotechnology and personalized medicines, we are still left pondering the mechanism and the need for informed consent. Technological transfer in today's world is rapid.

Therefore, any ethical issues faced by developed countries are transferred to the developing countries along with the new technology. However, since developing countries like Pakistan lack mechanisms to recognize and handle such issues, they assume even more alarming proportions here. The one significant success story in the area of bioethics from Pakistan is in addressing the menace of organ trade through the organ transplantation law. This particular law highlights the impact of ethical practices on not only the lives of ordinary citizens, but also on the reputation of the country among the international community.

Acknowledgement

I would like to thank Ms. Amenah Jafarey and Dr. Nisreen Feroz Ali for going through the drafts of this chapter and providing invaluable feedback regarding its content, relevance and comprehension from the viewpoint of medical students and recent graduates. Special thanks to Ms Anika Khan for painstakingly proofreading this chapter.

References

1. Sass Hans-M. Fitz Jahr's 1927 Concept of Bioethics. *Kennedy Inst Ethic*. December 2007; 17 (4): 279-295.
2. Reich WT. The "Wider View": Andre Hellegers's passionate, integrating intellect and the creation of bioethics. *Kennedy Inst Ethic J*. March 1999; 9 (1):22-25.
3. Aksoy S. The Religious Tradition of Ishaqibn Ali Al-Ruhawi: The Author of the First Medical Ethics Book in Islamic Medicine. *JISHIM*. 2004; 3 (5):9-11.
4. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 5thed. New York City, NY: OUP; 2001.
5. Fox RC, Swazey JP. *Observing Bioethics*. New York: OUP; 2008.
6. Moazam F, Jafarey AM. Pakistan and biomedical ethics: report from a Muslim Country. *Camb Q HealthC Ethic*. July 2005; 14 (3): 249-255.
7. Personal communication with Program Coordinator of the AKU Masters program.
8. List of National Bioethics Committee Members. Available from: <http://nbcpakistan.org.pk/members.html>
9. National Bioethics Committee of Pakistan. Guidelines for stem cell research. Available from: http://nbcpakistan.org.pk/wp-content/uploads/2012/05/Protocol-Guidelines_for-Stem-Cell_Research.pdf.
10. National Bioethics Committee of Pakistan. Guidelines for Physician Pharma Interaction. Available from: <http://nbcpakistan.org.pk/wp-content/uploads/2012/05/Guidelines-For-Healthcare-Professionals-PPI-Guidelines.pdf>.
11. Moazam F. Families, Patients and Physicians in Medical Decisionmaking: A Pakistani Perspective. *Hastings Cent Rep*. 2000 November-December; 30 (6): 28 – 37.
12. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. USA: OUP. 1986.
13. Katz J. *The Silent World of Doctor and Patient*. New York: The Free Press; 1984.
14. Jafarey AM, Farooqui A. Informed consent in the Pakistani milieu: the physician's perspective. *J Med Ethics*. 2005 February; 31 (2): 93-96.
15. Gostin OL, ed. *Public Health Law and Ethics: A Reader*. 2 ed. New York: UC Press; 2010 Tarasoff v. Regents of the University of California, 118 Cal. Rptr.129 (Cal. 1974) (Tarasoff I), modified by Tarasoff v. Regents of the Univ. of Cal., 551 P.2d 334 (Cal. 1976) (Tarasoff II).
16. I. M. Kennedy. The Karen Quinlan case: problems and proposals. *J Med Ethics*. 1976 March; 2(1): 3-7.

17. Onwuteaka-Philipsen BD, Brinkman-Stoppelenburg A, et al. Trends in end-of-life practices before and after the enactment of the euthanasia law in the Netherlands from 1990 to 2010: a repeated cross-sectional survey. *Lancet*. 2012 September 8; 380 (9845): 908-15.
18. Albert Jonsen, Mark Siegler, William Winslade. *Clinical Ethics: Practical Approach to Ethical Decisions in Clinical Medicine*. 7 ed. USA: McGraw-Hill; 2010.
19. Gordon DuVal, Leah Sartorius, Brian Clarridge, et al. What triggers requests for ethics consultations? *J Med Ethics*. 2001 April; 27: i24-i29.
20. Kamal, R. Establishing a clinical ethics committee: 5 year experience in Pakistan. Presentation at the World Congress of Bioethics, Brazil 2002.
21. Clinical Research Milestones. Available from: <http://firstclinical.com/milestones/?date-1800-1899>.
22. Sheridan Libraries. Major codes from then and now. USA, Baltimore: JHU. (Updated: Apr 5, 2013). Available from: <http://guides.library.jhu.edu/content.php?pid=23699&sid=190558>.
23. Permissible Medical Experiments. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10: Nuremberg October 1946–April 1949*. Washington: U.S. Government Printing Office (n.d.). *Bioethics, The Nuremberg Code*. 2: 181- 182.
24. George J Annas; Michael A Grodin, eds. *The Nazi doctors and the Nuremberg Code: human rights in human experimentation*, New York: OUP; 1992. Available from: <http://books.google.com.pk/>.
25. Digging up Japan's past. Deafening silence: An investigation into wartime atrocities, but the media keeps strangely quiet. *The Economist*. 2011 February 24; Tokyo. Available from: <http://www.economist.com/node/18237081>.
26. Watts J. Tokyo Victims of Japan's notorious Unit 731 sue. *Lancet*. 2002 August 24; 360 (9333): 628.
27. Beecher, Henry K. Laying Ethical Foundations for Informed Consent. *New Engl J Med*. 1966 June 16; 274 (24): 1374–1360. Republished with commentary in the series *Public Health Classics*. Harkness J, Lederer SE, Wikler D. *Laying Ethical Foundations for Clinical Research*. *Bull. World Health Organ*. 2001; 79 (4): 365–366. Available from: <http://www.scielosp.org/pdf/bwho/v79n4/v79n4a12.pdf>.
28. Final Report of the Tuskegee Syphilis Study Legacy Committee. University of Virginia Health Systems. 1996. Available from: http://www.hsl.virginia.edu/historical/medical_history/bad_blood/report.cfm.
29. Tanne JH. President Obama apologises to Guatemala over 1940s syphilis study. *News, BMJ*. 2010 October 4; 341: c5494.
30. Declaration of Helsinki. Seoul: World Medical Association; October 2008. Available from: <http://www.wma.net/en/30publications/10policies/b3/index.html>.
31. The Belmont Report. HHS.gov. 1979 April 18. Available from: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.
32. International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: CIOMS; 2002. Available from: https://docs.google.com/viewer?url=http://%3A%2F%2Fcioms.ch%2Fpublications%2Flayout_guide2002.pdf.
33. Qureshi H, Munir, M A. Survey of Institutional Ethical Review Committees (IERC's) in Pakistan. Presented at the National Research Ethics Workshop, Centre on Biomedical Ethics and Culture, SIUT, November 17-17, 2012.
34. Jafarey AM. Informed Consent: views from Karachi. *East. Mediterr. Health J*. 2006; 12 (Suppl. 1): S50-S55.
35. Thompson DF. Understanding Financial Conflicts of Interest. *NEJM*. 1993 August 19; 329 (8): 573-576.
36. Faden R, Shebaya S. *Public Health Ethics*. SEP. 2010 Apr 12. Available from: <http://plato.stanford.edu/entries/publichealth-ethics/>.
37. Mill JS. Gray J. editor. *On Liberty & Other Essays*. 2nd ed. New York: OUP; 1998.
38. Haines W. Consequentialism. *Internet Encyclopedia of Philosophy*. IEP. 2006 March 24. Available from: <http://www.iep.utm.edu/conseque/>.
39. Declan Walsh. Taliban block vaccinations in Pakistan. *New York Times*. 2012 June 18. Available from: <http://www.nytimes.com/2012/06/19/world/asia/taliban-block-vaccinations-in-pakistan.html>.
40. International Health Regulations 2005. World Health Organization. Available from: <http://www.who.int/ihr/en/>.
41. Reichert TA, et al. The Japanese Experience with Vaccinating School Children against Influenza. *New Engl J Med*. 2001 March 22; 344: 889-896. Available from: <http://www.nejm.org/doi/full/10.1056/NEJM200103223441204>.

42. Naqvi SAA. et al. Socioeconomic Survey of Kidney Vendors in Pakistan. *Transpl Int.* 2007 November; 20 (11):934-39.
43. Moazam F, Zaman RM, and Jafarey AM. Conversations with Kidney Vendors in Pakistan: An Ethnographic Study. *Hastings Center Report* 39. 2009 (3): 29-44.
44. Baqir SS. Organ trade ordinance. *Dawn.com*: 2007 September 4. Available from: <http://archives.dawn.com/2007/09/04/top7.htm>.
45. Moazam F, Jafarey A, Shirazi B. To Donate a Kidney: Public perspectives from Pakistan. *Bioethics.* 2012 October. doi:10.1111/bioe.12010.
46. Dollars for Doctors: How Industry Money Reaches Physicians. *Pro Publica.* Available from: <http://www.propublica.org/series/dollars-for-docs>.
47. No free lunch. 2012 October 22. Available from: www.nofreelunch.org.
48. Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA.* 2000 January 19; 283 (3): 373-380.
49. Studdert DM, Mello MM, Brennan TA. Financial Conflicts of Interest in Physicians' Relationships with the Pharmaceutical Industry-Self-Regulation in the Shadow of Federal Prosecution. *N Engl J Med.* 2004 October 28; 351: 1891-1900.
50. Ibid 47.
51. Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. *Am J Med.* 2005 Aug; 118 (8): 881-884.
52. Lexchin J. Interactions between physicians and the pharmaceutical industry: what does the literature say? *CMAJ.* 1993 November 15; 149 (10): 1401-1407.
53. Fugh-Berman A, Ahari S. Following the Script: How Drug Reps Make Friends and Influence Doctors. *PLoS Med.* 2007 April 24; 4 (4): e150. doi:10.1371/journal.pmed.0040150.
54. O'Reilly KB. As CME funding shifts from industry, others foot the bill. *Amednews.* 2011 September 12. Available from: <http://amednews.com/article/20110912/profession/309129948/2/>.
55. Prabhala A, Krishnaswamy S. Why Novartis case will help innovation. *The Hindu*; 2013 April 15. Available from:
56. Woodward C. New US law applies 'sunshine' to physician payments and gifts from drug, device industries. *CMAJ.* 2010 July 13; 182 (10): E467-E468. Available from: <http://www.cmaj.ca/content/182/10/E467.full.pdf+html>.
57. Interactions with Pharmaceutical Industry Representatives. Chicago, USA: AMA. Available from: <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/business-management-topics/interactions-pharmaceutical-industry-representatives.page>.
58. Godlee F, ed. A sunshine act for Europe. *BMJ.* 2011 October 13; 343: d6593.
59. Khan MM. Why physicians should not have any contact with pharmaceutical companies? *J Pak Med Assoc.* 2007 November; 57 (11): 572-3.
60. National Bioethics Committee of Pakistan. Guidelines for Physician Pharma Interaction. 2010 June 1. Available from: http://nbc-pakistan.org.pk/assets/ppi_guidelines_may_2011-1-final-copy-on-PHRC-website.pdf.
61. Ibid 60
62. Hotz RL. Scientists Create Synthetic Organism. *WSJA.* 2010 May 21.
63. Muehlenberg B. How many parents would your child like? *MercatorNet*; 2012 August 6. Available from: http://www.mercatornet.com/family_edge/view/11078/.
64. Gallagher J. Three-person IVF 'is ethical' to treat mitochondrial disease. *BBC News.* 2012 June 12. Available from: <http://www.bbc.co.uk/news/health-18393682>.
65. Meirow D, Schenker JG. The current status of sperm donation in assisted reproduction technology: Ethical and legal considerations. *J Assist Reprod Genet.* 1997 March; 14 (3): 133-138.
66. McLachlan HV, Swales JK. Exploitation and commercial surrogate motherhood. *Human Reproduction and Genetic Ethics. Hum Reprod Genet Ethics*; 2001; 7 (1): 8-14.
67. 23andMe, the world's trusted source of personal genetic information. Available from: www.23andme.com
68. Mello MM, Wolf LE. The Havasupai Indian Tribe Case - Lessons for Research Involving Stored Biologic Samples. *N Engl J Med.* 2010 Jul 15; 363 (3): 204-7.
69. Privacy and Progress in Whole Genome Sequencing. Presidents Commission for the Study of Bioethical Issues. 2012 October. Available from: <http://bioethics.gov/cms/node/764>.

70. Botkin JR. Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis. J Law Med Ethics. 1998 Spring; 26 (1): 17-28.
71. Informed Consent Form Template for Consent for Storage and Future Use of Unused Samples. WHO. 2012. Available from: http://www.who.int/rpc/researchethics/informed_consent/en/ .
72. Browne A. India fights US basmati rice patent. The Observer. 2000 June 25. Available from: <http://www.guardian.co.uk/world/2000/jun/25/anthonybrowne.theobserver> .
73. Hyat K. Depending on desperation. The News. 2012 May 23. Available from: <http://jang.com.pk/thenews/may2010-weekly/nos-23-05-2010/enc.htm#1> .

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www.nlm.nih.gov/hmd/greek/greek_oath.html

Open source document.

The Hippocratic Oath

The Hippocratic Oath (Ορκος) is perhaps the most widely known of Greek medical texts. It requires a new physician to swear upon a number of healing gods that he will uphold a number of professional ethical standards. It also strongly binds the student to his teacher and the greater community of physicians with responsibilities similar to that of a family member. In fact, the creation of the Oath may have marked the early stages of medical training to those outside the first families of Hippocratic medicine, the Asclepiads of Kos, by requiring strict loyalty.

Over the centuries, it has been rewritten often in order to suit the values of different cultures influenced by Greek medicine. Contrary to popular belief, the Hippocratic Oath is not required by most modern medical schools, although some have adopted modern versions that suit many in the profession in the 21st century. It also does not explicitly contain the phrase, "First, do no harm," which is commonly attributed to it.

Hippocratic Oath

I swear by Apollo the physician, and Asclepius, and Hygieia and Panacea and all the gods and goddesses as my witnesses, that, according to my ability and judgment, I will keep this Oath and this contract:

To hold him who taught me this art equally dear to me as my parents, to be a partner in life with him, and to fulfill his needs when required; to look upon his offspring as equals to my own siblings, and to teach them this art, if they shall wish to learn it, without fee or contract; and that by the set rules, lectures, and every other mode of instruction, I will impart a knowledge of the art to my own sons, and those of my teachers, and to students bound by this contract and having sworn this Oath to the law of medicine, but to no others.

I will use those dietary regimens which will benefit my patients according to my greatest ability and judgment, and I will do no harm or injustice to them.

I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion.

In purity and according to divine law will I carry out my life and my art.

I will not use the knife, even upon those suffering from stones, but I will leave this to those who are trained in this craft.

Into whatever homes I go, I will enter them for the benefit of the sick, avoiding any voluntary act of impropriety or corruption, including the seduction of women or men, whether they are free men or slaves.

Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.

So long as I maintain this Oath faithfully and without corruption, may it be granted to me to partake of life fully and the practice of my art, gaining the respect of all men for all time. However, should I transgress this Oath and violate it, may the opposite be my fate.

Translated by Michael North, National Library of Medicine, 2002.

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First published: 16 September 2002

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<http://www.pmdc.org.pk/Ethics/tabid/101/Default.aspx>
Open source document.

Pakistan Medical & Dental Council Code of Ethics of Practice for Medical and Dental Practitioners



Code of Ethics for Medical and Dental Practitioners

Made in exercise of the powers conferred by Section 33 of Pakistan Medical & Dental Council Ordinance, 1962 and approved by the Council in its meeting held on 11th July, 1968 at Karachi, and revised by the Council in its 48th session held on 6th and 7th December 1974 at Lahore; and revised in its 97th session held on 29th and 30th December 2001 at Islamabad.

Code of Ethics – 2001

Introduction

The Medical and Dental Council of Pakistan exists to maintain the register of Medical and Dental practitioners, regulate the standards of medical practice, protect the interests of the patients, supervise medical education, and give guidelines on ethical issues.

The medical profession is best regulated internally by the doctors themselves. With this privilege comes the responsibility, that doctors regulate their professional affairs through the Pakistan Medical and Dental Council, in the most effective way.

Both doctors and their patients have the right for making independent decisions. However, the code of ethics provides a set of principles prescribed by the Pakistan Medical and Dental Council, which doctors can use as guidelines in the varying situations, in line with their judgment, experience, knowledge and skills. Whilst the principles guiding medical practice rarely change, application of these principles to new situations will require frequent revision and publication.

This revised Code of Ethics have been prepared by the active participation of the honourable members of the Council. The assistance provided by Prof. Syed M. Awais and Prof. Jamsheer Talati during all stages of preparation of this document is highly appreciated.

The draft was approved by the Council in its 97th session held on 29th and 30th December 2001 at Islamabad, with the recommendation that draft will be circulated among the members of the Council and any recommendations received within one month will be included. Most of the recommendations received from the members have been incorporated in the draft. The final draft was approved by Executive

Committee during its meeting on 15th August, 2002.

Prof. Muhammad Hayat Zafar

President,

Pakistan Medical and Dental Council

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The abbreviation; “RMDP” will be used to indicate Registered Medical and Dental Practitioner (s), throughout the document.

1.0-Preamble ([Back to Contents](#))

History and Legal Framework

The Pakistan Medical and Dental Council (PMDC) Code of Ethics outlines the ethical principles and standards which determine the responsibilities and conduct of Medical and Dental professionals registered with the PMDC.

This Code of Ethics made in exercise of the powers conferred by Section 33 of Pakistan Medical & Dental Council Ordinance, 1962, is a revision of the code of ethics approved by the Council in its meeting held on 11th July, 1968 at Karachi, and subsequently revised by the Council in its 48th session held on 6th – 7th December 1974 at Lahore. This revision has been approved by the Council in the 97th session held on 29th and 30th December 2001 at Islamabad.

2.0- Jurisdiction of the Pakistan Medical and Dental Council (PMDC) ([Back to Contents](#))

The Pakistan Medical and Dental Council was duly constituted under the Medical & Dental Council Ordinance No. XXXII, 1962, in June 1964 and is empowered to:

1. Look after Public interest – by maintaining proper medical/dental standards.
2. Supervise Medical/Dental Education in the country.
3. Maintain a register of qualified doctors and dentists, qualifying from duly recognized institutions.
4. Take such disciplinary actions, which may be required for criminal convictions or serious professional misconduct of a doctor. The Council is not an Association or a Union for protecting professional interests.

3.0-Purpose ([Back to Contents](#))

- 3.1 The code is intended to provide guiding principles for use in every day practice for the Registered Medical and Dental Practitioners (RMDP) in their roles in regard to patients, students, community, colleagues, researchers and citizens (people).
- 3.2 The Code of Ethics is a public document which endeavours to educate its members and the public on professional ethics. It is intended for the welfare and protection of the individuals and societies with which the profession interacts. It states the responsibility of professionals to society and individuals; and the rights of an individual. It serves public interest.
- 3.3 When a Registered Medical or Dental practitioner’s conduct or practice and consequently registration, are questioned, these are the principles and standards against which s/he will be judged.

The Code of Ethics provides general guidelines, and any disciplinary committee designated by the PMDC will judge each case on its merits. This is not a comprehensive document and interpretation will depend upon circumstances. The Registered Medical and Dental Practitioner will be given opportunity to justify their actions to a Disciplinary Committee.

4.0- Applicability ([Back to Contents](#))

This Code is applicable to all registered Medical and Dental Practitioners.

5.0- Oath Of Medical And Dental Practitioners ([Back to Contents](#))

Adapted from the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948; and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968; and the 35th World Medical Assembly, Venice, Italy, October 1983; and the 46th World Medical Association General Assembly, Stockholm, Sweden, September 1994, and the Islamic Medical Association Oath for Muslim Doctors.]

At the time of being admitted as a member of the medical profession:
I solemnly pledge myself to consecrate my life to the service of humanity;
I will give to my teachers the respect and gratitude which is their due;
I will practice my profession with conscience and dignity;
The health of my patient will be my first consideration;
I will respect the secrets which are confided in me, even after the patient has died;
I will maintain by all the means in my power, the honour and the noble traditions of the medical profession;
My colleagues will be my sisters and brothers; and I will pay due respect and honour to them.
I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient;
I will protect human life in all stages and under all circumstances, doing my utmost to rescue it from death, malady, pain and anxiety. To be, all the way, an instrument of Allah's mercy, extending medical care to near and far, virtuous and sinner and friend and enemy.”
I make these promises solemnly, freely and upon my honour

6.0-Duties of Medical and Dental Practitioners (International Code of Medical Ethics) ([Back to Contents](#))

Drawing on the Declaration of Geneva, the WMA formulated a more detailed code of ethics which was approved by the 3rd Assembly of the WMA meeting in London in 1949. The International Code of Medical Ethics was subsequently amended in 1968 by the 22nd Assembly of the WMA in Sydney and again in 1983 by the 35th Assembly held in Venice. The text, as amended, reads as follows:

Duties of Physicians in General

A physician shall always maintain the highest standards of professional conduct and should actively participated in continuous Medical Education.

A physician shall not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients.

A physician shall, in all type of medical practice, be dedicated to providing competent medical services in full technical and moral independence, with compassion and respect for human dignity.

A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

The following practices are deemed to be unethical conduct:

1. Self advertising by physicians, unless permitted by the laws of the country and the Code of Ethics of the Pakistan Medical Association.

2. Paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring a patient to any source.

A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences.

A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

A physician shall use great caution in divulging discoveries or new techniques or treatment through non-professional channels.

A physician shall certify only that which he has personally verified.

Duties of Physicians to the Sick

A physician shall always bear in mind the obligation of preserving human life.

A physician shall owe his patients complete loyalty and all the resources of his science.

When ever an examination or treatment is beyond the physician's capacity he should summon another physician who has the necessary ability.

A physician shall preserve absolute confidentiality on all he knows about his patient even after the patient has died.

A physician shall give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

Duties of Physicians to each other

A physician shall behave towards his colleagues as he would have them behave towards him.

A physician shall not entice patients from his colleagues.

A physician shall observe the principles of the "Declaration of Geneva" approved by the World Medical Association.

7.0- Medical Ethics and Islam [\(Back to Contents\)](#)

In Islam, human beings are the crown of creation and are Allah's viceregents on earth. They are endowed with reason, choice and responsibilities, including stewardship of other creatures, the environment and their own health. Muslims are expected to be moderate and balanced in all matters, including health. Illness may be seen as a trial or even as a cleansing ordeal, but it is not viewed as a curse or punishment or an expression of Allah's wrath. Hence, the patient is obliged to seek treatment and to avoid being fatalistic.

Islamic bioethics is intimately linked to the broad ethical teachings of the Holy *Qur'an* and the tradition of the Prophet Muhammad (Peace be upon him), and thus to the interpretation of Islamic law. Bioethical deliberation is inseparable from the religion itself, which emphasizes continuities between body and mind, the material and spiritual realms and between ethics and jurisprudence. The *Qur'an* and the traditions of the Prophet Muhammad (Peace be upon him) have laid down detailed and specific ethical guidelines regarding various medical issues. The *Qur'an* itself has a surprising amount of an accurate detail regarding human embryological development, which informs discourse on the ethical and legal status of the embryo and fetus before birth.

Islamic bioethics emphasizes the importance of preventing illness, but when prevention fails, it provides guidance not only to the practicing physician but also to the patient. The physician understands the duty to strive to heal, acknowledging Allah as the ultimate healer. Islamic bioethics teaches that the patient must be treated with respect and compassion and that the physical, mental and spiritual dimensions of the illness experience be taken into account.

The main principles of the Hippocratic oath are, although acknowledged in Islamic bioethics, but the invocation of multiple gods in the original (Greek) version, and the exclusion of any god in later (Western) versions, have led Muslims to adopt the Oath of the Muslim Doctor, which invokes the name of Allah. It appears in the 1981 Islamic Code of Medical Ethics, which deals with many modern biomedical issues such as organ transplantation and assisted reproduction. In Islam, life is sacred: every moment of life has great value, even if it is of poor quality. The saving of life is a duty, and the unwarranted taking of life a grave sin. The *Quran* affirms the reverence for human life in reference to a similar commandment given to other monotheistic peoples: “On that account We decreed for the Children of Israel that whosoever killed a human being it shall be as if he had killed all humankind, and whosoever save the life of one, it shall be as if he saved the life of all humankind.” This passage legitimizes medical advances in saving human lives and justifies the prohibition against both suicide and euthanasia.

The Oath of the Muslims Doctor includes an undertaking “to protect human life in all stages and under all circumstances, doing [one’s] utmost to rescue it from death, malady, pain and anxiety. To be, all the way, an instrument of Allah’s mercy, extending medical care to near and far, virtuous and sinner and friend and enemy.”

Islamic bioethics is an extension of Shariah (Islamic Law), which is itself based on 2 foundations: the *Qur’an*, whose basic impulse is to release the greatest amount possible of the creative moral impulse and is itself “a healing and a mercy to those who believe” and the Sunna (the aspects of Islamic Law based on the Prophet Muhammad’s (Peace be upon him) words of acts).

To respond to new medical technology, Islamic jurists, informed by technical experts, have regular conferences at which emerging issues are explored and consensus is sought. Thus, over the past few years, these conferences have dealt with such issues as organ transplantation, brain death, assisted conception, technology in the intensive care unit and even futuristic issues such as testicular and ovarian grafts.

If secular Western bioethics can be described as rights-based, with a strong emphasis on individual rights, Islamic bioethics is based on duties and obligations (e.g. to preserve life, seek treatment), although rights (of Allah, the community and the individual) do feature in bioethics, as does a call to virtue (Ihsan).

8.0 The Teaching of Medical Ethics [\(Back to Contents\)](#)

The Curriculum Committee of the PMDC will ensure that adequate information on the Code of Ethics is included in the undergraduate medical college curriculum; and that case studies have been prepared and disseminated to provide guidance to practitioners.

- 8.1 The goal of teaching medical ethics is to improve the quality of patient care by enhancing professional performance through a consideration of the clinician’s values, beliefs, knowledge of ethical and legal construct, ability to recognize and analyse ethical problems, and interpersonal and communication skills; and consideration of the patient. Students should be able to identify, analyse and should attempt to resolve common ethical problems of medical and clinical nature.
- 8.2 All medical and dental colleges running MBBS and BDS Courses, College of Physician and Surgeons of Pakistan and Universities running the Postgraduate Medical Courses in Pakistan are advised to incorporate medical ethics into their curriculum.
- 8.3 Relevant books and journals should be made available in the central and departmental Libraries of the medical institutions, and publication of papers on issue related to medical ethics must be encouraged.
- 8.4 The PMDC exhorts its members to develop strategies for dissemination of information about

ethics and ethical issues to their colleagues and students, public and patients; and specifically when teaching medical students.

9.0 –Expectations ([Back to Contents](#))

The PMDC expects each practitioner to:

- 9.1 Promote the fundamental principle of responsibility of physicians to the right of individuals and societies to stated standards of professional competence, appropriate care, conduct and integrity of Medical and Dental Practitioners;
- 9.2 Uphold the ethical principles of medical practice i.e. autonomy, beneficence, non-maleficence, and justice;
- 9.3 Ensure the protection of individuals (patients) against harassment, discrimination and exploitation;
- 9.4 Take their responsibilities as a teacher seriously.
- 9.5 Be responsive to cultural and religious sensitivities; and
- 9.6 Declare in a transparent manner, any potential conflict of interest.
- 9.7 Inculcate these values in students, through instruction and role modeling.
- 9.8 Promote the education of the public on (a) health issues and (b) their rights to quality care.
- 9.9 Ensure continuation of practice only when in normal physical and mental health
- 9.10 Bring colleagues to comply with these generally accepted norms of practice and expose physicians and dentists deficient in competence, care and conduct

10.0-Fundamental Elements of Patient – Physician Relationship ([Back to Contents](#))

Patients share with physicians the responsibility for their own health care.

- 10.1 The patient has the right to receive information from physicians and to discuss the benefits, risks, costs of appropriate treatment alternatives, and optimal course of action. Patients are also entitled to obtain copies or summaries of their medical records, to have their questions answered, and to receive independent additional professional opinions.
- 10.2 The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients (or next of kin) may accept or refuse any recommended medical treatment in writing.
- 10.3 The patient has the right to courtesy, respect, dignity, and timely responsiveness to his or her “health needs”.
- 10.4 The patient has the right to confidentiality.
- 10.5 The patient has the right to continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient.

11.0- Ethical Standards of Professional Competence, Care and Conduct ([Back to Contents](#))

11.1 Conduct of Medical practitioner:

In all dealings with patients, it is expected that the interest of the patient and the advantage to the patient's health will be the major consideration to influence the practitioners' conduct (defined as character and behaviour as a citizen and professional) towards them. The physician patient relationship should be developed as one of trust

11.1.1 A Professional shall always maintain and demonstrate a high standard of professional conduct by:

- Being in conformity with the principles of honesty and justice.
- Not permitting motives of profit to influence (free and independent exercise of) professional judgment
- Working with colleagues in ways that best serve patient's interests.
- Not paying or receiving any fee or any other consideration solely to procure the referral of a patient or for prescribing or referring a patient to any source.
- Maintaining the honourable tradition by which the physician is regarded as a friend to all persons of any class, caste, colour, religion, sex, ethnicity, occupation, creed, religion and social status.
- Being honest, factual, objective, unbiased as a reviewer for scientific material for publication; for funding purposes; and when providing reference, ensuring that comments are honest, justifiable, unbiased, and contain evidence on the subject's competence, performance, reliability, and conduct, taking steps to ensure the accuracy of any public communications including the communication of degrees, institutional affiliation, extent of services offered, and credentials.

11.1.2 The RMDP will not assist an unregistered person to practice / teach medicine or dentistry, or associate professionally with such a person performing the functions of a practitioner. which knowingly will make a registered practitioner liable to disciplinary action. This does not preclude a medical practitioner from imparting proper training to medical students, nurses, midwives and other paramedical personnel, provided the doctors concerned keep a strict supervision over such individuals when treating patients.

11.1.3 The RMDP will not knowingly make false, misleading or deceptive statements.

11.1.4 The RMDP will deal honestly with colleagues, respecting their rights and privileges and that of other health professionals.

11.1.5 Forgery, theft, fraud, indecent behavior or any other offence liable to be seen as moral turpitude is liable to disciplinary action.

11.1.6 The RMDP shall use great caution in divulging discoveries or new techniques or treatment through non-professional channels.

11.1.7 A physician shall owe his patients complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond the physician's capacity he should consult another physician who has the necessary ability.

11.1.8 Prisoners who are ill must be treated in the same manner as other sick people. However, doctors have a right to take appropriate precautions if they think

there is a possibility of physical violence by the patient.

Where a suspect refuses consent to a medical examination, the doctor unless directed to the contrary by a court of Law, should refuse to make any statement based on his observation of the suspect other than to advise the police whether or not the suspect appears to require immediate treatment or removal to hospital.

This does not of course, preclude the doctor from making a statement in Court based on such observation in circumstances where the accused later gives his consent to disclosure.

- 11.1.9 Doctors should normally ask permission from a patient before making a physical examination. In the case of minors, the child's guardian should be present or give permission for the examination. For any intimate examination the patient irrespective of age, is entitled to ask for a attendant to be present. Such requests should be acceded to whenever possible.
- 11.1.10 Personal relationships: Any form of sexual advance to a patient with whom there exists a professional relationship is professional misconduct. A RMDP's professional position must never be used to pursue a relationship of an emotional or sexual nature with a patient, the patient's spouse, or a near relative of a patient.
 - Sexual misconduct: Sexual contact with patient or patient's spouses, partners, parents, guardians, or other individuals involved in the care of the patient is liable to lead to exclusion from the register.
- 11.1.11 RMDP will ensure that they do not engage in harassment of any person, including employees, patients, students, research assistants and supervisees. [The following constitute harassment: when single, multiple, or persistent acts of abusive verbal language, demeaning speech, insult in front of juniors, sexual innuendoes, sexual solicitation, physical advance, throwing objects, and other threatening unacceptable gestures.]. Physicians should not use language that will interfere with the work of others.
- 11.1.12 Abuse of professional knowledge, skills and privileges is unacceptable conduct: Any registered medical/dental practitioner found guilty of causing an illegal abortion or prescribing drugs in violation of the Dangerous Drugs Act, or who becomes addicted to a drug, or is convicted of driving under the influence of alcohol or any other drug, is liable to be suspended or have his/her name removed from the Register.
- 11.1.13 No RMDP should accept illegal gratification.

11.2 Care:

The patient-physician or patient-dental practitioner relationship constitutes a fiduciary obligation, requiring physicians to be responsible to serve the interests of patients above their own financial or other interests.

- 11.2.1 The practitioner is expected to provide a quality of care for a patient which is timely, compassionate and respects human privacy and dignity, is non-discriminating and does not exploit vulnerable situations. Gross negligence in respect of professional duties may justify suspension or removal from the Register.
- 11.2.2 The RMDP will bear in mind the obligation of preserving life and will not discriminate on the basis of age, sex, gender, class, race, ethnicity, national origin,

religion, sexual orientation, disability, health conditions, marital discord, domestic or parental status, criminal record, or any other applicable bias as proscribed by law, and ensure that personal beliefs do not prejudice patient care.

- 11.2.3 The RMDP should not exploit persons over whom they have direct or indirect supervisory, evaluative, management or other authority, such as students and patients, supervisees, employees or research participants; whether for personal, professional or economic reasons.
- 11.2.4 The RMDP should delegate to a student or other physician, only those responsibilities that such persons, based on their education, training and experience, can reasonably be expected to perform either independently or with the level of supervision provided.
- 11.2.5 The RMDP shall additionally:
- Identify themselves to patients whom they are treating
 - Treat all patients with dignity and respect,
 - Listen to patients and respect their views,
 - Give patients (and provided patient agrees, family members) information (about their illness) in a way that they can understand,
 - Respect the rights of patients to be involved fully in decisions about their care,
 - Ensure that conflict of interest does not prevent them from performing their professional work in an unbiased manner,
 - Adhere to veracity (truth telling) as judged in the patient's interest.
- 11.2.6 Details of Information: Patients do not always fully understand the information and advice given to them by doctors. They should be encouraged to ask questions. These should be answered carefully in non-technical terms if necessary with or without information leaflets. The aim is to promote understanding and to encourage compliance with recommended therapy. The doctor should keep a note of such explanation and it is felt that the patient still does not understand it may be advisable to ask the patients permission to speak to a relative.
- 11.2.7 Maternity care: Registered medical practitioners who agree to undertake the antenatal and delivery care of a woman should clearly inform her, in advance, the arrangements for delivery. In Pakistan, according to law a pregnancy can be terminated only if there lies a serious risk to the life of the pregnant women.
- 11.2.8 Procedures: Patients undergoing procedures or treatment of any sort have the right to be informed as to which doctor or doctors are to be involved.
- 11.2.9 Fees: Doctors fees should be appropriate to the service provided. Patients are entitled to ask how much a doctor is going to charge.
- 11.2.10 Second Opinion: Patients are entitled to a second or further medical opinion about their illness. If requested, RMDP must either initiate or facilitate a request for this and provide the information necessary for satisfactory referral.
- 11.2.11 Communication with Patients: Many complaints to the council refer to lack of communication, or discourtesy, on the part of the doctor. Where differences have arisen between the doctor and the patient or the patients relatives there is much to be gained and rarely anything to be lost by the expression of regret by the doctor. Feeling that any such expression would amount o an admission of liability may have inhibited doctors. This is not necessarily so.

11.3 Competence

The RMDP will attempt to maintain the highest levels of competence in their work more specifically the skill in diagnosing, clinical decision-making, planning, implementation, monitoring and evaluation of intervention and teaching; and will accept responsibility for their actions.

They will therefore:

- 11.3.1 Only undertake tasks for which they are qualified by virtue of education, training or experience; and know their limitations.
- 11.3.2 Keep abreast of latest information about their subject through continuing education;
- 11.3.3 Ensure that their approach to patient management is consistent with current research, literature and practice;
- 11.3.4 Have an approach that favours competent clinical care through a careful assessment of the patient's problem, based on elicitation and analysis of the patient's history and physical examination; careful decisions on need for further investigation and request for additional consultation, appropriate management and prompt action where indicated, an approach that shuns internet prescribing or telephonic prescribing except when the physician is cognizant of the individuals past medical history
- 11.3.5 Acquire the knowledge and skills to provide proper training and supervision to their students so that such persons perform services responsibly, competently and ethically; and will be honest and objective in the assessment and certification of performance of students supervised;
- 11.3.6 Monitor and maintain an awareness of the quality of the care provided by himself/herself through a review of carefully recorded data; and respond constructively to assessments by self and peers which identify need for further training or education;
- 11.3.7 Recognise the realistic efficacy of investigation and medication and use technology and medicine only where appropriate;
- 11.3.8 Restrict prescription of drugs, appliances or treatments to only those that are beneficial to the patient.
- 11.3.9 Treatment without direct patient contact. Prescribing of medications by practitioners requires that the physician should demonstrate that a documented history and physical examination and drug reaction history are available; that there has been a sufficient dialogue between the patient and the doctor on options in management, and a review of the course of the illness and side effects of the drug.
- 11.3.10 The PMDC accepts that in an emergency, during on call or cover call, or when in a partnership the case records are available, a physician may prescribe a new prescription without seeing the patient.

12.0-Confidentiality ([Back to Contents](#))

The physician has a right to and should withhold disclosure of information received in a confidential context, whether this be from a patient, or as a result of being involved in the management of the patient, or review of a paper, except in certain specific circumstances where s/he may carefully and selectively disclose information where health, safety and life of other individual/s may be involved.

- 12.1 The practitioner cannot seek to gain from information received in a confidential context (such as a paper sent for review) until that information is publicly available.
- 12.2 There is no legal compulsion on a doctor to provide information concerning a criminal abortion, venereal disease, attempted suicide, or concealed birth regarding his patients to any other individual or organization. When in doubt concerning matters, which have a legal implication, the practitioner may consult his/her legal adviser
- 12.3 The professional medical record of a patient should not be handed over to any person without the consent of the patient or his/her legal representative. Generally speaking, the state has no right to demand information from the doctor about his patient, save when some notification is required by statute such as in the case of communicable diseases. When in doubt, a legal advisor should be consulted.
- 12.4 A presiding judge, may, despite the physician claiming the knowledge and communication is confidential overrule this contention and order or direct the witness to supply the required information. The doctor has no option but to comply unless willing to accept imprisonment for contempt of court.

13.0-Conflicts of interest ([Back to Contents](#))

A conflict of interest “is a set of conditions in which professional judgement concerning a primary interest tends to be unduly influenced by a secondary interest.” In the clinical context the primary obligation of physicians is to their patients, whereas in the research context scientific knowledge may be the primary interest. A secondary interest may be of a financial nature, but it may also consist of personal prestige or academic recognition and promotion. In research involving patients, the research interests, although often in concordance with patients’ interests, are secondary to clinical care and may conflict with it. A typical example of conflict of interest related to personal gain in physician self-referral. In above mentioned definition the reference to “a set of conditions” is important – having a conflict of interest is an objective situation and does not depend on underlying motives. Stating that someone has a conflict of interest does not imply a moral condemnation per se. It is the person’s action in the context of a particular situation or a lack of transparency that may be a cause for concern.

- 13.1 The practitioner must act in patient’s best interests when making referrals and providing or arranging treatment or care. No inducement, gift or hospitality which may affect or be seen to affect judgment may be accepted. Neither will a practitioner offer such inducements to colleagues.
- 13.2 Financial or commercial interests in organizations providing health care or in pharmaceutical or other biomedical companies, must not affect the way that patients are prescribed, treated or referred.
- 13.3 Financial or commercial interest in an organization to which a patient is to be referred for treatment or investigation must be declared to the patient
- 13.4 Before taking part in discussions about buying goods or services, any relevant financial or commercial interest which the practitioner or the practitioner’s family might have in the purchases, must be declared.

14.0-Truth Telling ([Back to Contents](#))

In the practice of medicine, truth telling involves the provision of information not simply to enable patients to make informed choices about health care and other aspects of their lives but also to inform

them about their situation. Patients may have an interest in medical information regardless of whether that information is required to make a decision about medical treatment.

The physicians should strive to create a “true impression” in the mind of the patient. Thus, truth telling requires that information be presented in such a way that it can be understood and applied. By contrast, deception involves intentionally leading another to adopt a belief that one holds to be untrue.

Patients should be told the truth because of the respect due to them as persons. Patients have a right to be told important information that physicians have about them.

15.0-Advertising ([Back to Contents](#))

- 15.1 When publishing or broadcasting information the practitioner must not make claims about the quality of services nor compare services with those provided by colleagues. Announcements must not, in any way, offer guarantees of cures, nor exploit patients’ vulnerability or lack of medical knowledge.
- 15.2 Published information about services must not put pressure on people to use a service, for example by arousing ill-founded fear for their future health. Similarly, services must not be advertised by visiting or telephoning prospective patients, either in person or through a deputy
- 15.3 Practitioners may announce any change of address or hours of practice in the local press either once in three papers or three times in the same paper, on three consecutive days, and the announcement should be made in a normal manner and not unduly prominently as by big advertisements.
- 15.4 Nameplates may be fixed at the residence and on the premises where the medical/dental practitioner practices and at his residence. The nameplate should not be ostentatious.

16.0-Certificates, Reports and other documents ([Back to Contents](#))

When RMDP are requested for certificates, medical reports birth or death certificates and any other documents, such documents should be factual to the best of their knowledge. Due care should be taken in regard to stating the date on which the patient has been examined.

17.0-Business and contractual obligations ([Back to Contents](#))

Physicians and dentists must ensure that they do not engage in any behaviour that negatively impacts directly or indirectly on patient care. Business and contractual obligations must never interfere with clinical decisions or negatively impact on patient care in any way. Physicians are discouraged from entering into business or other arrangements that include financial incentives; sharing of fees including refund based on successful outcomes and payments for referral of patients for laboratory investigations or other procedures except when a partnership is publicly known to exist.

18.0-Consent ([Back to Contents](#))

Consent is the “autonomous authorization of a medical intervention by individual patients.” Patients are entitled to make decisions about their medical care and have the right to be given all available information relevant to such decisions. Patients have the right to refuse treatment and to be given all available information relevant to the refusal.

Consent may be explicit or implied. Explicit consent can be given orally or in writing. Consent is implied

when the patient indicates a willingness to undergo a certain procedure or treatment by his or her behaviour. For example, consent for venipuncture is implied by the action of rolling up one's sleeve and presenting one's arm. For treatments that entail risk or involve more than mild discomfort, it is expected that the physician will obtain explicit rather than implied consent.

Signed consent forms document but cannot replace the consent process. There are no fixed rules as to when a signed consent form is required. Some hospitals require that a consent form be signed by the patient for surgical procedures but not for certain equally risky interventions. If a signed consent form is not required, and the treatment carries risk, clinicians should seriously consider writing a note in the patient's chart to document that the consent process has occurred.

When taking consent the physician should consider issues of adequate disclosure, the patient's capacity, and the degree of voluntariness.

In the context of patient consent, "disclosure" refers to the provision of relevant information by the clinician and its comprehension by the patient. Disclosure should inform the patient adequately about the treatment and its expected effects, relevant alternative options and their benefits and risks, and the consequences of declining or delaying treatment and how the proposed treatment (and other options) might affect the patient's employment, finances, family life and other personal concerns.

"Waiver" refers to a patient's voluntary request to forego one or more elements of disclosure. For example, a patient may not wish to know about a serious prognosis (e.g., cancer) or about the risk of treatment.

"Capacity" refers to the patient's ability to understand information relevant to a treatment decision and consequences of a complying or not complying with a treatment decision. A person may be "capable" (have adequate capacity) with respect to one decision but not with respect to another. When any doubt exists, a clinical capacity assessment by a third party may be required. In addition to assessing general cognitive ability, specific capacity assessment, determines the patient's ability to appreciate information and implications of action.

"Voluntariness" refers to a patient's right to make health care choices free of any undue influence. However, a patient's freedom to make choices can be compromised by internal factors such as pain and by external factors such as force, coercion and manipulation. In exceptional circumstances -- for example, involuntary admission to hospital -- patients may be denied their freedom of choice; in such circumstances the least restrictive means possible of managing the patient should always be preferred. Clinicians can minimize the impact of controlling factors on patients' decisions by promoting awareness of available choices, inviting questions and ensuring that decisions are based on an adequate, unbiased disclosure of the relevant information.

Special circumstances affecting the consent process are listed below

18.1 The Unconscious Patient

Consent may be implied or assumed on the grounds that if the patient were conscious they would consent to their life being saved.

18.2 The Violent Patient

A doctor asked to examine a violent patient is under no obligation to put him/herself in danger but should attempt to persuade the person concerned to permit an assessment as to whether any

therapy is required.

18.3 The Mentally ill

The Mentally ill Of the doctor is in any doubt as to the patient's capacity to consent it is advisable to seek specialist opinion as well as discussing the matter with parents, guardians, or relatives.

18.4 The Mentally Handicapped

The Mentally Handicapped The doctor should attempt to obtain consent but, depending on the degree of handicap, may have to consult with the patient's parents or guardians, and, in particularly difficult cases to obtain a second opinion.

18.5 Children

Children are entitled to considerate and careful medical care as are adults. If the doctor feels that a child will understand a proposed medical procedure, information or advice, this should be explained fully to the child. Where the consent of parents or guardians is normally required in respect of a child for whom they are responsible, due regard must be given to the wishes of the child. Also, the doctor must never assume that it is safe to ignore the parental/guardian interest.

19.0-Teaching Photography and Consent ([Back to Contents](#))

- 19.1 Medical and dental students must identify themselves by name and must obtain permission from patients before examining them. It is advisable to limit the number of students examining any one patient.
- 19.2 The taking of photographs or videos for instructional purposes also requires permission. As far as possible these photographs and videos should be done in such a manner that a third party cannot identify the patient concerned. If the patient is identifiable, he or she should be informed about the security, storage, and eventual destruction of the record.

20.0-Research Ethics and Consent ([Back to Contents](#))

When conducting medical research involving human subjects, investigators should remember their obligations with respect to individual patients. Ethical conduct of research requires that a human subject must participate willingly, having been adequately informed about the research and given consent; that there is a favourable balance between the potential benefit and harm of participation; and that protection of vulnerable people is ensured. The validity of findings must address questions of sufficient importance to justify any risks to participants. In any clinical trial there must be genuine uncertainty as to which treatment arm offers the most benefit, and placebo controls should not be used if equally effective standard therapies exist. When doubt exists, researchers should consult the existing literature and seek the advice of experts in research ethics.

- 20.1 All research projects involving human subjects, whether as individuals or communities, or the use of fetal material, embryos and tissues from the recently dead, should be reviewed and approved by an Ethical Review Committee of the institution before the study begins.
- 20.2 It is essential that written consent be obtained if patients are to be involved in clinical trials. The aims and methods of the proposed research, together with any potential hazards or discomfort,

should be explained to the patient. The Consent document must be clearly written using non-technical language as to be understandable to subjects and use local language in addition wherever applicable.

- 20.3 In situations where study subjects are too young or too incapacitated, as well as the mentally ill or unconscious person, consent to take part in research may be unobtainable. Research is best avoided unless it can be shown to be relevant and potentially beneficial to the patient and there is no objection from parents or relatives.
- 20.4 Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person.
- 20.5 The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, and the confidentiality of the patient's information.
 - 20.5.1 Research results must always preserve patient **anonymity** unless permission has been given by the patient to use his or her name.
- 20.6 Volunteers and patients may be paid for inconvenience and time spent, but such payment should not be so large as to be an inducement.
- 20.7 Refusal to participate in research must not influence the care of a patient in any way.
- 20.8 Declaration of Helsinki The PMDC supports the resolutions and draws attention to the Declaration of Helsinki adopted by the 18th World Medical Assembly and revised by the 48th World Medical Assembly.

21.0-Organ Transplantation and Consent ([Back to Contents](#))

- 21.1 A doctor involved in organ transplantation has duties towards both donors and recipients.
- 21.2 Prior to considering transplant from the dead donor, brain death should be diagnosed, using currently accepted criteria, by at least two independent and appropriately qualified clinicians, who are also independent of the transplant team. If family of the dead donor cannot take care of the funeral of donors body, then the transplant doctor involved in organ transplantation shall take care of transplantation and funeral.
- 21.3 Living donors should be counseled as to the hazards and problems involved in the proposed procedures, preferably by an independent physician.

22.0-Adoption ([Back to Contents](#))

Doctors should remember that in cases of proposed adoption there are several parties involved all of whom need continued support and counseling. Pregnant women who are considering giving up their babies for adoption should be helped to approach advisory bodies / attorneys as the circumstances may be.

23.0-Resource Allocation ([Back to Contents](#))

All resource allocation decisions must be transparent and defensible. Questions of resource allocation are difficult and can pose practical and ethical dilemmas for clinicians. The unequal allocation of a scarce resource may be justified by morally relevant factors such as need or likelihood of benefit. To what extent the physician's fiduciary duty toward a patient should supersede the interests of other patients and society as a whole is also a matter of controversy. However, the allocation of resources on the basis of clinically irrelevant factors such as religion or gender is prohibited.

24.0-End-of-Life Care ([Back to Contents](#))

End-of-life care requires control of pain and other symptoms, decisions on the use of life-sustaining treatment, and support of dying patients and their families.

- 24.1 Futile treatment need neither be offered to patients nor be provided if demanded. A treatment is qualitatively futile if it “merely preserves permanent unconsciousness or fails to end total dependence on intensive medical care or when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of reported empiric data) that a medical treatment has been useless.
- 24.2 The physician is not compelled to accede to demands by patients or their families for treatment thought to be inappropriate by health care providers.

25.0-Genetics in Medicine ([Back to Contents](#))

Molecular genetics is concerned with the process by which the coding sequences of DNA are transcribed into proteins that control cell reproduction, specialization, maintenance and responses. Inherited or acquired biologic factors that result in an error in this molecular information processing can contribute to the development of a disease. Medical genetics involves the application of genetic knowledge and technology to specific clinical and epidemiologic concerns. Although many common diseases are suspected of having a genetic component, few are purely genetic in the sense that the genetic anomaly is adequate to give rise to the disease. In most cases, genetic risk factors must be augmented by other genetic or environmental factors for the disease to be expressed. Moreover, the detection of a genetic anomaly not help us to predict the severity with which the syndrome will expressed.

Certain ethical and legal responsibilities accompany the flood of genetic knowledge into the current practice of medicine. This is because of 3 general characteristics of genetic information: the implications of genetic information are simultaneously individual and familial; genetic information is often relevant to future disease; and genetic testing often identifies disorders for which there are not effective treatments or preventive measures.

26.0- Procedures for Review of the Code ([Back to Contents](#))

The Code will be reviewed every five years by a committee set up by the PMDC.

27.0-Procedure for Enforcement of the Code ([Back to Contents](#))

The PMDC may take disciplinary action (on the basis of recommendations of a disciplinary committee) against members who violate the code.

- 27.1 Process for initiating complaints
 - 27.1.1 The Secretary will take note of complaints received from lay public or fellow-practitioners, mentioning the details of complainant.
 - 27.1.2 Process for addressing complaints: Complaints will be examined and investigated by the standing Disciplinary Committee of the PMDC which will forward its recommendations

to the Executive Council. The Disciplinary Committee will investigate possible infractions, and will seek relevant information from persons and records, in order to reach a decision on whether the code has been violated. If disciplinary action is requested, the case will be referred to the Executive Committee.

- 27.1.3 The Executive Committee will recommend to the Council prescriptive action in disciplining the member. The Executive Committee will review and endorse the Disciplinary Committee actions if it agrees, or ask for a further review of the case by another or the same or expanded Disciplinary Committee or disagree or modify the recommendations on the basis of available information. It will then pronounce the disciplinary decision.
- 27.1.4 The Full Council will be informed of the decision in the next Full Council meeting. The PMDC ratifies the decision.
- 27.1.5 The matter will be referred to the Court if needed.
- 27.1.6 Disciplinary action: The disciplinary action may either be an admonition, a temporary suspension for a specified period or life long expulsion from membership of the PMDC. The PMDC will when making the latter decision will consider whether it is in public interest to retain the name of the practitioner on the Register The PMDC expects that every member will report infringement of the code by a fellow member in the interest of patient. In minor infractions, it is expected that members will advise the individual on a one on one basis. If this fails to bring about corrective behaviour the matter should be brought to the attention of the PMDC.
- 27.2 Constitution of the Disciplinary Committee The Disciplinary Committee should be constituted as per regulations for Registration of Medical & Dental practitioners.
- 27.3 A claim of ignorance cannot be made as the PMDC regulations will be sent to every Registered Medical or Dental Practitioners and will be available on the website.
- 27.4 Publication The name of individuals, who have been expelled from the register of the PMDC, will be displayed in the PMDC Gazette and regional health authorities will be informed.

28.-Glossary ([Back to Contents](#))

Competence

Ability and skill in diagnosing, clinical decision-making and management.

Care

The quality of interaction with a patient.

Conduct

Character and behavior as a citizen and professional

Veracity

Accuracy of statement

Fiduciary

Held or given in trust

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Farhat Moazam, Aamir M. Jafarey, "Pakistan and biomedical ethics: Report from a Muslim country," *Cambridge Quarterly of Healthcare Ethics*, vol. 14, no. 3 (2005): 249–255.

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Pakistan and Biomedical Ethics: Report from a Muslim Country

Special Section: International Voices

Farhat Moazam, Aamir M. Jafarey

The Islamic Republic of Pakistan has a population of over 145 million people, about 95% of whom are Muslims (approximately 20% Shi'i and the rest Sunni). Although it has a few large cities such as Karachi, almost 65% of the country is still rural, with a per capita income of \$408 per year. The overall literacy rate is estimated to be 41.5% but is much lower for women in many of the provinces.¹ Pakistan has a complex culture with many ethnic groups and socioeconomic strata, but overall the society is characterized by hierarchical systems in both private and public domains. The population is religious and family centered with the "family" understood as extending beyond the nuclear; it is not uncommon to have three generations residing under one roof or within close proximity to each other and pooling their resources.

As is the case in many developing countries, Pakistan is experiencing an increase in high-tech tertiary-level medicine such as advanced cardiology, state-of-the-art cardiac surgery, major joint replacements, reproductive technology, and organ transplantation. Healthcare is provided free of charge through public (government-run) clinics and hospitals, but these institutions are generally understaffed, overcrowded, and inefficient, and many have a reputation for providing substandard care. In the past decade there has been a proliferation of private healthcare institutions, especially in the larger cities, that utilize a fee-for-service system. However, due to existing poverty and an absence of national health coverage or health insurance schemes, many remain beyond the reach of a majority of the population.

The primary aim of this paper is to give an account of the current status of biomedical ethics in Pakistan. This report, we hope, will address Alastair Campbell's statement that little is found so far about "non-Western world views in the Bioethics literature."² This account will also highlight the ways in which Pakistanis and their medical community, products of a culture in which Muslim beliefs and values are central to comprehension of ethics and morality, are beginning to interface with the secular language of contemporary bioethics.

Birth of Bioethics in Pakistan

In Pakistan it is primarily members of the medical community, many trained in Western institutions, who took the lead in introducing modern biomedical ethics into the country. The first formal move in this direction occurred in 1984 at the Aga Khan University (AKU) in Karachi, the first private university to be established in Pakistan. Biomedical ethics was introduced in the curriculum of medical students at AKU by the Chairman of the Department of Community Health Sciences³ and later extended into the courses of the University's School of Nursing. In the initial stages, the teaching consisted primarily of a focus on the "four principles" as elaborated by Beauchamp and Childress in their *Principles of Biomedical Ethics*, but with the involvement of clinical faculty, it gradually incorporated "real" cases encountered in clinical

practice in the AKU teaching hospital.⁴ By 1997, workshops and courses focusing on various aspects of bioethics and “local” ethical dilemmas also became mandatory elements of postgraduate clinical training for residents in all AKU programs, a first for the country.⁵ In 2001, the Pakistan Medical and Dental Council (PMDC), the certifying body for all graduating physicians and dentists, stipulated that biomedical ethics must be included in the medical curricula. However this is still not the case in a majority of the country’s medical colleges and many still limit themselves to a few didactic lectures on the subject during rotation of students through community health sciences.

Ethics Review Committees (ERC) are a relatively new phenomenon in Pakistan, although there is a gradual move within a few private healthcare institutions to initiate such committees.⁶ Approval by ERC or Institutional Review Boards is still not mandatory for obtaining research funding from local sources, but there is a dawning realization in the medical community that this step is now essential to attract and participate in collaborative research projects with institutions in the United States, European Union, and international organizations such as World Health Organization (WHO), and a requirement for any publications in international indexed journals.⁷

Standing Hospital or Clinical Ethics Committees are still a rarity in Pakistan. To date, the AKU Hospital is the only institution with a formal ethics consultation service, which is one of the functions of its Hospital Ethics Committee (HEC), initiated in 2000.⁸ The constitution of HEC and its consultation services were primarily driven by plans to apply for approval by the Joint Commission on International Accreditation (JCIA) of the United States, which considers availability of such services as a mandatory requirement for their accreditation of hospitals. Recently a small hospital in the private sector, the Patel Hospital in Karachi, has also instituted a Hospital Ethics Committee, motivated exclusively by the concern of physicians and administration about the ethics of some aspects of medical practice in the institution.

In the late 1990s, a nonindexed journal, the Pakistan Journal of Medical Ethics, began publication with the objective of promoting medical ethics. Unfortunately due to insufficient financial support and inadequate organizational structure only half a dozen sporadic issues have been published since then.

Developments in Research Ethics

In Pakistan a growing interest in biomedical ethics is reflected in the increase over the past few years in the number of workshops and conferences related to bioethics being organized in both the public and private sectors. In Pakistan, as in the rest of the world, there has been a great demand for research-ethics-related programs. This is due to the fact that most international funding agencies and many peer-reviewed scientific journals now require ethical review of research protocols and manuscripts for acceptance. These events provide valuable experience to the researchers, increasing their chances for obtaining funding as well as publication. In addition, with the rapid increase in collaborative research between industrialized nations and developing countries, it is easier to find international funding for activities connected to research ethics and there is a willingness on the part of faculty (especially from established centers in North America) to help run research ethics workshops. This is exemplified by the Global Forum on Bioethics in Research (GFBR), a collaborative effort of several international organizations, which aims at strengthening research ethics in developing countries. The GFBR has selected Karachi, Pakistan, as the venue for their annual meeting scheduled for 2006.

Similar to the experience of other developing countries, Pakistan has benefited from the international focus on research ethics as a prominent feature of the “globalization” of contemporary bioethics. In the past five years, a handful of Pakistani physicians from a private university in Karachi have taken the opportunity to pursue fellowships and master’s degree programs in Australia, Canada, and the United

States through funding from the National Institutes of Health and the Fogarty International Center meant particularly for enhancing research ethics capacity in developing world scientists. The Eastern Mediterranean Regional Organization (EMRO) of WHO has also expressed an interest in strengthening research ethics capacity and is funding a situation analysis of research capacity in the countries of the region, including Pakistan. One of the authors (Jafarey) is currently a participant in this project but has extended the survey beyond research to general bioethics capacity in Pakistan.

Developments in Clinical Ethics

Also on the rise, and considered as more relevant by a greater number of healthcare professionals in Pakistan, is an interest in what constitutes ethical medical practice in light of the changing face of medicine due to advances in medical science and biotechnology. Sessions in medical conferences organized by medical colleges and universities as well as medical organizations are being frequently devoted to clinical ethical dilemmas and how these are to be addressed against the background of indigenous cultural and religious values and local socioeconomic realities. In the period of 2003–2004 alone such sessions were arranged by the Dow Medical College, Liaquat National Hospital and Postgraduate Institute, the Aga Khan University, the Pakistan Society of Urological Surgeons, the National Research Institute of Fertility Control, and the National Skin Center. The Sindh Institute of Urology and Transplantation, located in Karachi, has regularly devoted at least one session to ethics in its biennial international conference for over a decade. The topics chosen for discussion have included ethical and economic factors influencing related kidney donation, treatment of infants with end-stage renal disease, views of Muslim scholars on organ transplantation and brain death, and Islamic perspectives on xenotransplantation.

What is striking in the explosive increase in conferences and seminars devoted to clinical ethics is that besides considering the “secular” aspects of bioethics including a language of the four bioethical principles, there is a growing emphasis on exploring traditional Muslim ethical sources and opinions of contemporary Muslim ulema (scholars) and jurists on a wide variety of topics including brain death criteria, issues connected to death and dying, discontinuation of ventilatory support, organ and xenotransplantation, abortions, reproductive technology, and cloning. In the spring of 2004, the Pakistan Islamic Medical Association (a nongovernmental organization) conducted a heavily attended medical symposium that included sessions on Islamic medical ethics and the ethical challenges posed by emerging technologies. The discussants included both physicians and invited Muslim scholars, and they covered issues as diverse as training in medical ethics, ethical issues connected to pharmaceutical marketing, physician–patient relationships, and Islamic views about assisted reproductive technologies.

In October 2004, one of the authors (Moazam) was invited to an international clinical ethics seminar held at the Aga Khan University in which speakers were invited from the United States and United Kingdom but also included national and regional religious scholars. She herself was requested by the organization committee to address Islamic sources in an understanding of what constitutes ethical conduct for physicians and other healthcare professionals. The response of the audience to her talk entitled “Foundational Concepts of Ethics in Islam” was noteworthy, as it was for other presentations that covered Islamic perspectives on abortions, Muslim juristic rulings on death and dying, and the role of Muslim physicians in the care of terminally ill patients.

Pakistan Medical and Dental Council Code of Ethics

The PMDC is the government regulating body that registers all graduates from medical and dental colleges in Pakistan. In 2002, it published a revised and extensive Code of Ethics for all practitioners and included a recommendation that education in bioethics be made part of the curricula. A review of the Code reveals an interesting mix of, and we believe a tension between, philosophically grounded elements of contemporary bioethics and moral values drawn from Islamic teachings. The four principles of contemporary bioethics (autonomy, beneficence, nonmaleficence, and justice) are stated in the Code as

being “fundamental elements” of the relationship between the patient and physician. Nevertheless, the point is also made that “if secular Western bioethics can be described as rights-based, with a strong emphasis on individual rights, Islamic bioethics is based on duties and obligations” of the physician. While discussing appropriate care of patients, the Code advises that the practitioner must “adhere to veracity (truth telling) as judged in the patient’s interest.” Practitioners are also reminded that “Islamic bioethics is intimately linked to the broad ethical teachings of the Holy Qur’an and the tradition of the Prophet Mohammad,” and that unlike “secular” oaths the “Oath of the Muslim Doctor” invokes “the name of Allah.”⁹

National Bioethics Committee of Pakistan

Based on a realization of the importance of bioethics, the government of Pakistan approved in January 2004 the constitution of a National Bioethics Committee (NBC) to be chaired by the Director General Health in the Ministry of Health, and with the Pakistan Health and Research Council (PHRC) acting as its secretariat. In the note circulated by the government, the NBC is stated as functioning as “an advisory body dealing with all aspects of bioethics in the health sector in the country.” It is expected to “promote and facilitate ethical health services delivery and health research,” and work through two subcommittees: the Research Ethics Committee and the Medical Ethics Committee. The recommended membership of 20–21 individuals includes 2 each of “Bio Scientists” and “Academics,” and 2 representatives from Universities/Medical Colleges. Also included are 1 each from the categories of General Practitioners, Nurses, Social Scientists, Lawyers, Religious Scholars, Industry, and the Human Rights Commission.¹⁰ A workshop was organized in Islamabad by the PHRC in March 2004 to work out details of the Terms of Reference for NBC, the final conclusions of which are awaited.

Recent Developments: Center of Biomedical Ethics and Culture

In the past decade, contemporary bioethics and questions about how it should interface with indigenous cultural and religious (Muslim) beliefs and moral values and socioeconomic realities has evoked a tremendous response within Pakistan. This interest has been largely spearheaded by the efforts of members of the medical community. These efforts, however, had been without tangible institutional support in the form of a dedicated department or center of biomedical ethics within either the public or private sector. In 2004, recognizing the need for an organizational structure dedicated to promoting discussion on these issues and fostering educational and research activities in bioethics, Adibul Hasan Rizvi, the Director and transplant surgeon of the Sindh Institute of Urology and Transplantation (SIUT) in Karachi, took the initiative to establish such a center.¹¹

The Center of Biomedical Ethics and Culture (CBEC), located on the premises of SIUT, was inaugurated on October 8, 2004, and received wide press coverage. The 300 invitees to the event included representatives from WHO and EMRO and faculty from the Center of Biomedical Ethics at the University of Virginia. Atta-ur-Rahman, Pakistan’s Federal Minister and Adviser to the Prime Minister on Science and Technology and Chairman of the country’s Higher Education Commission, attended as chief guest. In his speech, Atta-ur-Rahman noted the importance and need for such a Center in Pakistan and promised support for its activities. He also informed the audience of the plans by the Higher Education Commission to establish an International Center of Bioethics in the country that would undertake “research and educational activities on both national and international levels.”¹²

The brochure circulated at the inauguration listed the primary goal of CBEC as being to serve as “an academic and intellectual national resource” and to assist in “capacity building of future faculty and staff in biomedical ethics” for the country. An important function of CBEC was stated to be to explore “the role of cultural, societal and religious norms in shaping indigenous value systems that are seminal components of human moral comprehension.” The audience was also provided information about a seminar and Intensive Course being planned by CBEC for the spring of 2005 entitled “Foundations of Moral Thought” that would include national and international bioethicists, sociologists, and Muslim

scholars as speakers.¹³ In particular, the speakers would explore the “historical contributions of Muslim philosophers, theologians, jurists and ulema” in fashioning “the chain of human moral thought.”

Conclusions

In many industrialized countries such as the United States, philosophers and theologians are considered to have played major roles in the birth of contemporary bioethics.¹⁴ This occurred at a time of rapid advances in medical science and technology that, while saving many more lives, was paradoxically also increasing public distrust of physicians and medical researchers and radically changing the face of interactions between healthcare professionals and patients. In the United States in particular, catalysts in the evolution of modern bioethics included profound social changes underway in the 1960s such as an increasing focus on individual rights, the civil rights movement, strong patient advocacy groups, the rise of feminism, and an assertive press and legal system.

The short history of a still nascent contemporary bioethics in Pakistan reveals the ways in which it is being influenced and molded by local values and existing realities that differ in significant ways from those in countries where modern bioethics was founded. The advent of bioethics as a subject of interest and relevance to healthcare professionals can be traced to the medical college and faculty of a private university in Karachi rather than to philosophical and theological discourse or public and legal pressures. The impetus for the growth in activities related to bioethics in Pakistan is primarily pragmatic and largely coming from members of the healthcare community, especially physicians, some (by no means all) of whom have received part of their medical training in the United States or the United Kingdom. Many of them are involved in tertiary care medical practice.

The soil of Pakistan like many other developing countries has been very receptive to biomedical advances that have brought with them a capacity for tertiary-level interventions extending from reproductive technology to organ transplantations. With this has come a growing realization among healthcare professionals that the biotechnology in Pakistan may be identical to that in the West but it is being applied in a country with a very different epistemology of what constitutes right and wrong and how this is to be determined. Reason is considered an important human faculty but many Pakistanis, Muslim physicians and laypersons alike, believe that it is an incomplete guide for chartering realms that extend beyond the purely “scientific.” In this view, when reflecting on morality and ethics, reason must take into account long-standing religious and cultural norms as well as an interpretation of Islamic law.¹⁵ We believe that the trajectory of bioethics in Pakistan will provide important cultural perspective that can serve to enrich the international discourse and ongoing activities in contemporary bioethics.

References

1. United Nations Development Program (UNDP). Human Development Report. 2004.
2. Campbell AV. Presidential address: Global bioethics — Dream or nightmare? *Bioethics* 1999; 13:183–90.
3. The Chairman at the time was Jack Bryant, an American public health physician with extensive experience in working in developing countries. He is also one of the drafters of the first ethical guidelines for biomedical research issued by the Council for International Organizations of Medical Sciences (CIOMS).
4. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 5th ed. New York: Oxford University Press, 2001.
5. At the time, one of the authors (Moazam) was the associate dean of the Aga Khan University postgraduate medical education (residency programs) and instrumental in making bioethics a mandatory part of resident education. For details of the evolution of bioethical activities at AKU, see Jafarey A. The bioethics group of the Aga Khan University, Karachi. *Issues in Medical Ethics* 2002; X: 165–6.
6. Besides AKU, which has had a standing committee to review institutional research proposals for a decade, another private university in Karachi, Ziauddin Medical University, has recently set up such a committee and another private sector institution, the Liaquat National Hospital and Postgraduate Institute, has expressed an interest in doing so. The web site of the Office of Human Research Protection (OHRP) of the U.S. Department of Health and Human Services currently lists eight Ethics Review Committees in Pakistan that are approved. Of these, three are located in universities and five are names of NGOs. Available from <http://www.hhs.gov/ohrp/>.
7. For a list of some of the articles related to bioethics from Pakistani authors see Hyder AA, Nadeem S. Health ethics in Pakistan: A literature review of its present state. *Journal of Health Population and Nutrition* 2001; 19:6–11.
8. For an account of how indigenous cultural and religious values inevitably influence ethics consultants, their deliberations, and actions, see Moazam F, Zaman RM. At the interface of cultures. *The Journal of Clinical Ethics* 2003; 14:246–58.
9. The Pakistan Medical and Dental Council. Code of Ethics for Medical and Dental Practitioners. 2002; Aug: 5–7, 12. The entire code of ethics is available from <http://www.pmdc.org.pk/ethics.htm>.
10. For details, see the Pakistan government document entitled “The Gazette of Pakistan, Published by Authority,” Part IV, Registered No. M.302, Ministry of Health, Islamabad 2004 Jan 12; 8–9.
11. The plans for the Center of Biomedical Ethics and Culture, its objectives, and activities were worked out between Dr. Adibul Hasan Rizvi and one of the authors (Moazam) over 2002–2004. She was subsequently offered, and accepted, the position of chairperson for the Center.
12. *Biomedical ethics, culture centre at SIUT*. *Dawn* 2004; 9:17.
13. The international speakers who have agreed to participate in the April 2005 Course include Jonathan Moreno, Director of the Center for Biomedical Ethics at the University of Virginia (UVA), Aziz Sachedina, Muslim scholar from the Department of Religious Studies, UVA, and Renee C. Fox, Annenberg Professor Emerita of Social Sciences at the University of Pennsylvania.
14. For a good discussion of the role and interaction of philosophy and religion in the evolution of bioethics in the United States, see Messikomer CM, Fox RC, and Swazey JP. The presence and influence of religion in American bioethics. *Perspectives in Biology and Medicine* 2001; 44:485–508.
15. For an elaboration of this concept, see Moazam F. Families, patients, and physicians in medical decision making: A Pakistani perspective. *Hastings Center Report* 2000; 30:28–7.

Clinical Ethics

2.1: Informed Consent

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Cases for Discussion

- **Case 1**

An adult woman with symptomatic gallstones is brought to the surgeon by her husband. After examination and going over the investigations, the doctor recommends laparoscopic cholecystectomy. Communication is primarily between the husband and the surgeon since he is the only one asking questions. The RMO brings out the consent form and the husband signs it.

What are the ethical and legal issues in this situation?

- **Case 2**

A 15 year old girl is brought to the ER with abdominal pain and is diagnosed with acute appendicitis needing appendectomy. She is accompanied by her parents.

What is the role of the patient in the informed consent process?

What is the role of her parents?

- **Case 3**

An unconscious male is brought to the ER by his wife and his brother after a road traffic accident. He is assessed by the neurosurgery team who decide on an emergency craniotomy to evacuate an expanding extradural hematoma.

Who gives consent: his brother, the patient's wife, the physician, or is no consent required in this situation?

What if the patient was brought in by a taxi driver and has no accompanying family/friend?

How does the process of informed consent take place?

- **Case 4**

A 75 year old mentally competent man is suffering from a rectal cancer that requires surgery. His sons and brothers bring the reports to a surgeon to confirm diagnosis and discuss the treatment plan. They plead with the surgeon not to tell the patient about the diagnosis of cancer and to proceed with surgery which involves colon resection and temporary colostomy, followed by reversal. They are willing to sign all consent documents.

How should the surgeon proceed?

Who should sign the informed consent?

What is the requirement in Pakistan law?

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Teaching Video

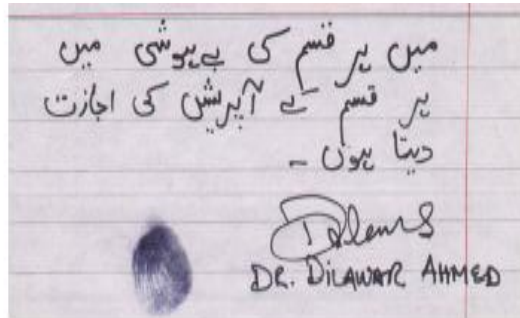
The Sound of Silence: <https://vimeo.com/51587494>

This movie explores cultural questions of informed consent from women in a hierarchical, male centred society. It raises issues of respecting and exploring the patient's wishes even when the individual appears disinterested. It also explores the issues of privacy, empathy and caring in the interactions between physicians and patients.

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Examples of Inappropriate and Appropriate Informed Consent Forms

Inappropriate Informed Consent



“I hereby give my permission for any type of operation to be performed on me under any type of anesthesia,” with a thumbprint and a doctor’s signature.

Appropriate Informed Consent

Consent to Surgery, Diagnostic Procedures, Transfusions or Other Medical Procedures

Patient Name: _____

Print patient name at top of form

I approve and direct Dr.(s) _____ or other doctors or dentists judged qualified by him or her to perform a _____.

Sedation and Anesthesia

Create sub-headings and separate

This procedure will be done with:

- ___ no sedation (medicines used to make you calm, drowsy, or fall asleep)
- ___ a small amount of sedation
- ___ moderate or conscious sedation
- ___ deep sedation
- ___ anesthesia (pain medicine that will keep you from feeling anything)

Define complex terms

The risks, benefits, alternatives and complications of sedation have been explained and my questions answered. I, the patient, or someone representing me, has approved the plan for sedation.

My doctor may need to do other procedures during this surgery or procedure. This could happen if he or she finds an unexpected condition. If my doctor feels it's needed, I agree to these added procedures. These would be done to avoid the risks of having a second surgery or procedure.

I understand the purpose of the surgery or procedure needed for my treatment. I know the practice of medicine, surgery, and dentistry is not an exact science. I know that no guarantee can be made about the outcome.

Reduced density of text

Increased white space

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Farhat Moazam, "Families, patients and physicians in medical decision making: A Pakistani perspective,"
The Hastings Center Report, vol. 30, no. 6 (2000): 28–37.

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Families, Patients, and Physicians in Medical Decisionmaking: A Pakistani Perspective

Farhat Moazam

In Pakistan, as in many non-Western cultures, decisions about a patient's health care are often made by the family or the doctor. For doctors educated in the West, the Pakistani approach requires striking a balance between preserving indigenous values and carving out room for patients to participate in their medical decisions.

After training and practicing as a physician in the United States for many years, I accepted an academic position at a medical university in Pakistan. One of my first experiences there was to tell two brothers sitting across the desk from me that all investigations indicated their elderly father had widespread metastatic cancer, and therefore not long to live. The patient, who lived with the oldest son and his family, was not present during this conversation, although an unmarried daughter, a daughter-in-law, and an adult grandson were. After listening attentively to what I had to say, and obviously upset at this news, one of the sons said, "We do not want him to know that he has cancer. How long he lives is in the hands of God in any case, and it is not right to make my father lose hope while he is so ill." He then added, "Doctor Sahib, tell us what we should do next. You know best. You are not just our doctor, you are like our mother."

In these words lies the essence of decisionmaking when illness strikes a member of the family in Pakistan. It is the family rather than the patient who takes center stage in this process. In the case of a conscious patient, the family and physician will generally protect the patient from the anxiety and distress associated with the knowledge of impending death. This is done by not disclosing the diagnosis or disclosing it in ambiguous terms. The "doctor sahib," (sahib has an Arabic root meaning "lord") remains the authority in matters relating to disease and medical interventions. She or he is often symbolically inducted into the family and is expected to direct rather than just facilitate medical management. In the final analysis, however, God, not man, controls life and death.

This model, in which religion and the extended family play a primary role in matters dealing with illnesses, particularly terminal illnesses, is shared by many Eastern cultures, but contrasts significantly with the situation prevalent in many western countries. In secular Western societies, patient autonomy is generally accepted as the cornerstone of medical ethics when it comes to choices involving medical care and end of life decisions. The competent patient is considered an autonomous and rational agent who is sovereign over her fate and the locus for all choices regarding therapeutic interventions¹—witness the fact that by 1991 more than forty states in the U.S. had enacted "living will" statutes that allow competent people to refuse therapeutic measures in the event of terminal illness even if they are no longer competent, and that trump opinions of family members and physicians. In that year also the federal Patient Self-determination Act went into effect, requiring that all adult patients admitted to a hospital be told of their right to formulate an advance directive.²

The principle of autonomy has also been extended to incompetent patients who do not have advance directives through court rulings and the legislature.³ The substituted judgment standard works on the premise that the personal autonomy of the once competent patient must be extended to her current state of incompetency, with the surrogate functioning as an instrument to determine what the patient would have wished done under the circumstances, if he or she were still competent.

The autonomy model is not without critics, however, especially in a pluralistic society. Joseph Carrese and Lorna Rhodes, for example, have noted that many Navajo consider advance care planning to violate their traditional values.⁴ Nor is the exclusion of families from decisionmaking universally valued. Empirical research by Leslie Blackhall and colleagues has shown that Korean and Mexican Americans, among others in the United States, feel that families not patients should hear a terminal diagnosis and be the primary decisionmakers.⁵

Undoubtedly the realities of American society, an amalgam of people from many different ethnic groups, have helped bring such issues to the forefront. In recent years, medical, bioethical, and legal literature has begun to address the need for families to have a greater role in medical decisionmaking.⁶ A number of court decisions and legislative actions in the last decade have moved toward giving families greater decisional authority in the area of disputes about terminal care as well.⁷ More importantly, almost 80 percent of the world's population resides outside North America and Western Europe. For many, families play a major if not primary role in therapeutic decisions, including end of life situations.

Medical decisionmaking in Pakistan offers interesting contrasts to secular societies. Although the country came into being as an independent nation in 1947, its people have longstanding cultural traditions and religious beliefs that place the family at the center of one's existence. Lives are spent within extended families in which power structures are clearly defined. Familial relationships are not merely horizontal but also vertical across three or more generations. In such societies, Arthur Kleinman notes, the individual is viewed as "sociocentrically enmeshed in inextricable social bonds, ties that make interpersonal processes the source of vital decisions."⁸ In Pakistan, family-centered decisionmaking works in tandem with an active, directive role assumed by the physician that stresses the principles of beneficence and non-maleficence rather than patient autonomy. In this deeply religious society, morality is rooted primarily in what is perceived as the religious obligations of the family and the physician toward the patient rather than stemming from a secular, reason-based philosophy that emphasizes the legal rights of individuals.

The following reflections on the interconnectedness of the patient and the family, the dominant role of the physician, and the impact of religious beliefs and socioeconomic realities on medical decisionmaking flow from my experience of having practiced both in the United States and, for more than a decade, in Pakistan.

Families: Ties that Bind

The family is the fundamental unit of society in Pakistan, a country with over 130 million people. Almost 65 percent of the population is rural, and 95 percent of the citizens are Muslims. In contrast to the pluralistic society of the United States, Pakistan offers a fairly homogenous milieu insofar as values and sociocultural norms are concerned. Religious belief plays a central role in the life of men and women from all social strata and is a major influence on all public and private activities. Historically, Islamic teachings have regarded all fields of human activity as coming under the umbrella of religion. There is no separation of state and religion, and no activity is considered purely secular in the life of a Muslim.⁹ Moral authority and a sense of right and wrong are derived from religious tenets.

Although the functioning of the judiciary is based on the British legal system, Article 198 of the Constitution of the Islamic Republic of Pakistan states that no law shall be enacted that is considered "repugnant" to the injunctions of Islam.¹⁰ Islam does not recognize a central church or religious

priesthood and ministries. Direction is sought through the Quran, the Muslim holy book considered to be the Word of God, and the Traditions, Sunna, of the Prophet Muhammad. These sources form the basis of Islamic law, the Shari'a that guides all private and public conduct, and is similar in many ways to the Jewish Halakhah. If no direct answer to a moral or ethical dilemma in personal life can be gleaned through the Shari'a, "subordinate sources," in the form of opinions from Muslim scholars or jurists, are sought.

For Muslims, religion defines the role of the individual, the family, and the physician in life passages including birth, illness, and death. It frames familial and filial responsibilities, obligations of physicians, decisions that involve end of life situations, and how death itself is to be viewed. This remains a seminal difference from many Western societies, in which moral direction for these events is usually sought through human reason, a concept rooted in the secular philosophy of Kant and Mill. Whereas rationalism fuels the ethical and legal discourse of human relationships in secular societies, in Pakistan religion and an interpretation of divine injunctions are the driving forces.

People generally live together in extended families, and it is not uncommon to have three generations living under one roof or in close proximity to each other. It is not unusual for children, particularly sons, to continue to live with their parents following marriage, leading to strong vertical, intergenerational relationships. Personal identity takes second place to the collective family identity and consciousness. Family obligations and harmonious living are considered moral imperatives, second in importance only to submission to the will of God. Discourses that revolve around the rights of individual members in a family, including what one "owes" to another or the issue of "rights" between parents and their children, are alien.¹¹ Mark Kuczewski's observation, while discussing the family's role in decisionmaking in the United States, that "medical ethics has rediscovered the family," would be incomprehensible to most Pakistanis.¹² In Pakistan, for the vast majority of the population, you are your family, and your family is you.

Family obligations are considered a moral injunction from God. Aging parents in particular are to be treated with patience and humility.¹³ The Prophet said, "the best beloved of God is one who loves his family the most."¹⁴ Increasing wisdom is attributed to advancement in years and the gray-haired "elders" of a family are to be respected and obeyed. Relationships and connectedness are defined through mutual trust, care, and obligations rather than competing rights of individual members. This forms the paradigm for the way humans must relate to one another within a family, not only in life but also when death is at hand. Concerns regarding "erosion of the patient's autonomy and subordination of the patient's interest to competing interests" of other members in the family would not resonate well in the social context of Pakistan.¹⁵ A legal concept of advance directives and living wills by an individual regarding her end of life care is alien to Pakistani cultural norms.

Family members generally avoid disclosure of terminal diseases like cancer to patients to avoid "burdening" them further and to allow "dying in peace." This is perceived as a form of caring, particularly toward elderly family members. "Death with dignity," oft repeated in English literature, is seldom raised as an issue in Pakistan. Members of the extended family with whom the patient resides generally undertake decisions regarding terminal care for both competent and incompetent patients. Nursing homes for those who are aged, terminally ill, or incompetent are unknown in Pakistan; such individuals are cared for at home by the family. Although affluent families may hire nurses for home care of a family member who is ill, care giving in most cases is a shared responsibility of the female members of the extended family. These may include a wife, unmarried daughters, or daughters-in-law. As families are both hierarchical and patrilineal, the oldest male member plays a pivotal role in major decisions, with a varying degree of input from the patient and other family members.

The physician is often “adopted” into the family unit by being referred to as mother, father, or older sibling. After being addressed by pediatric patients in the United States as “Doctor” for many years, it was a novel experience for me when children in my clinic in Pakistan were instructed to call me “Aunty” or “Doctor Aunty.” Male physicians are referred to as “uncles.” Parents and even grandparents accompanying the child, while conversing with me, often expressed their respect by referring to me as being “like a mother” or an “older” sister to them. It is interesting that in this strongly patriarchal society, the mother is awarded a position of respect that is superior to all other relationships. This is based on the Prophet having said that janat (paradise) lies under the feet of a mother. Therefore, equating a female physician with a mother is indicative of reverence and can confer an incredible degree of authority.

The phenomenon of placing a health care professional in the role of a family member has received some attention in psychosocial literature emanating from Pakistan. Riffat Zaman, an American-trained psychologist, notes that the “cultural pattern” is generally one in which “one confides in and trusts family members rather than strangers.”¹⁶ Thus “even when the therapist is a stranger to begin with,” the patient eventually begins to see the therapist in “the role of a family member.” In her opinion, Pakistani patients will often feel more comfortable seeking therapy from someone known to them or their family rather than a stranger. Similarly, I believe that awarding physicians an adoptive kinship reflects a collectivistic culture (as opposed to one that is individualistic) that experiences life primarily as a mosaic of interdependent family relationships that extend from the cradle to the grave.

Within the extended family, relationships are generally well defined based on gender and age. From childhood, members are taught to respect authority, a characteristic that has also been observed in other non-Western cultures.¹⁷ In Pakistan, according to Zaman, help is usually sought from an authority figure within the family, usually a parent or older sibling, who is expected to be not only supportive and facilitative, but also directive in the advice given.¹⁸ This is construed as a sign of caring rather than as an intrusive act. Zaman, when comparing her experience as a psychotherapist in the United States to that in Pakistan, states that the “idealized neutrality” of the therapist in the West does not hold up well in such a culture. According to her, in Pakistan, at the end of a session patients wait expectantly for the therapist to provide a “solution on which they should or would act.”

In my own practice I often sensed a prototype of a parent-child interaction, with many families expecting me to play the role of an “elder.” In the United States I was sometimes asked by a patient, “What would you do if you were in my place?” In Pakistan this is more likely to be phrased “What do you think I should do?” Interaction with a physician thus takes the form of recourse to an authority figure and not merely a consultation with a medical expert.

The Physician: An Instrument of God

In Pakistan, the physician is held in high esteem by a society that respects authority and condones hierarchical systems. This is also true of other oriental societies, such as Japan.¹⁹ In Pakistan, however, reverence and respect toward physicians is due not only to their knowledge and scientific expertise but also to the historical position accorded the art and science of medicine in Islam. The privileged position of physicians is derived through a historical understanding of the healer as an instrument of divine mercy. This became clear to me through several personal experiences caring for patients in Pakistan.

One was a conversation I had with the father of a frail newborn in the neonatal intensive care unit. The baby was critically ill and close to death. He had a perforated intestine, but there was a small chance that surgical intervention might save his life. The father interrupted my explanation—a product of my own “Western” education in the necessity for seeking the decision maker’s informed consent—of the patient’s disease and the nature and risks of the surgery we were contemplating. He told me that I did not need his permission because while he believed in God up there (he pointed to the sky), here on earth he held the same trust in me. In effect, he was signifying to me that just as he could not question God’s wisdom and

His divine plans, when it came to decisions regarding corporal matters of his ill child he put the same faith in me, the physician. Another instance was my conversation with a grateful mother taking her child home after a long hospitalization and several surgical procedures. After thanking me for my surgical, scientific expertise, she added a caveat. It was clear, she said, that I was a good doctor because God had put shifa (the power of healing) in my hands. Again, I was perceived as having a kind of connection with God in my role as a physician.

According to al-Ruhavi, a famous Muslim physician of the ninth century, a physician “imitates the acts of God as much as he can.” One of the Arabic words for a physician is Hakim. It means one who has knowledge and wisdom and is also a name for God.²⁰ According to a Muslim scholar of the fourteenth century, “after performing God’s worship and the basic duties of Islam, there is no greater service to God than to treat patients.”²¹ In Islam, many scholars have historically assigned a high religious priority to medicine, second only to ritual worship. Al-Ghazali, an eleventh century Muslim theologian and philosopher, considered the profession of medicine to be a fard-kifaya, collective duty, of Muslims, in which some members must assume this religious responsibility for the good of the community.²²

Under the auspices of the Islamic Organization of Medical Sciences, a conference on Islamic medicine was held in Kuwait in 1981 to mark the beginning of the fifteenth Islamic century.²³ Participants, consisting of physicians and theologians of Muslim countries, met with a view that there was a need to integrate Islamic medical ethics with modern medicine. The Quran and Sunna were used as the basis for arriving at a consensus. The conference ended with the formulation of a detailed Islamic Code of Medical Ethics that described the practice of medicine as “an act of worship” and the physician as an “instrument of God.”²⁴ This reinforces the belief that respect and reverence for the physician are due not only for her scientific knowledge and expertise but also for her religious responsibility, a striking contrast to a secular understanding of the physician as a well-trained expert who provides a service to consumers and clients in a contractual relationship.

There are strong religious prohibitions in Islam against physician-assisted suicide or direct actions that hasten death. This is related to a Quranic verse that for one who takes a life it is “as if he killed all humankind.”²⁵ The language of the Islamic Code of Medical Ethics is one of obligations and duties of the physician with a lesser focus on the rights of the patient. The code states that “it is the process of life that the doctor aims to maintain and not the process of dying,” and prohibits the physician from taking any “positive measure to terminate the patient’s life.” It forbids ending the life of a patient “even when motivated by mercy.” The issue of a patient’s right to request assistance or take steps to end his or her life is therefore not an option in Islam.

The code mentions that physicians must obtain consent from patients. However, when urgent intervention is required “to save life” the physician is stated to be morally obligated to proceed with what he or she believes is essential. This is based on a rule by Muslim jurists that “necessities override prohibitions.”²⁶ Among many Muslim physicians this is applied in instances when saving a life may require medical intervention without consent from the patient. Pakistani physicians will also usually turn to family members for consent when a patient is reluctant to accept an intervention that is considered essential to save his or her life. For example, an anxious, elderly woman with congestive heart failure needed an urgent coronary bypass, but developed dangerous arrhythmias each time the issue of this major surgery was broached with her. Following a discussion with her son, with whom she lived, the consent for the surgery was obtained from him. The patient was merely informed that the surgeon needed to do “a test,” and the surgery was undertaken uneventfully. Such collusion between the family and the physician would have been ethically and legally problematic in many Western societies. In this case, at the time of discharge, the patient, having been informed of the subterfuge following her recovery from surgery, warmly thanked the surgeon for proceeding with the necessary intervention and saw her son’s decision to assume responsibility for consenting on her behalf as an act of filial love.

Although family members are taken into confidence, physicians in Pakistan generally use substantial discretion when it comes to disclosing a grave prognosis or terminal illness to the patient. In the absence of a legal requirement or a tradition of living wills, physicians rarely disclose terminal disease to the patient or often do so in ambiguous terms. Portions of the Islamic Code of Medical Ethics dealing with the issue of disclosure state that the patient has “a right” to know about his illness, but that the physician’s “way of answering should be tailored to the particular patient in question.” The physician is advised to find “suitable vocabulary” depending on the situation and delete “frightening nomenclature.” If necessary, “coinage of new names, expressions or descriptions” is suggested. This is very much the case in Pakistan, where physicians tend to interpret informed consent contextually, tailoring the extent, time, and nature of disclosure based on their and the family’s belief as to what and how much the patient should be told.

Avoiding full disclosure of terminal disease and using ambiguous terminology has also been reported from other societies, particularly in regard to cancer. In an international survey of the attitude of physicians in revealing the diagnosis of cancer to patients, fewer than 40 percent of oncologists from Africa, Hungary, Japan, Portugal, Italy, and Spain were reported as using the word cancer when talking to patients.²⁷ Commonly substituted words included “growth,” “tumor,” “mass,” etc. Although recent studies, particularly in Japan, indicate a trend toward greater acceptance of revealing the true diagnosis to the patient, a reluctance for full disclosure is still not uncommon in many cultures. The 1995 survey by Carrese and Rhodes reported a strong Navajo cultural belief that presenting such information to patients is detrimental to their health and welfare “negative words” could hurt the patient.²⁸

In Pakistan, reluctance to reveal the diagnosis of terminal disease appears to be largely based on the family’s concern to protect the patient from additional distress. In my experience, at times this mirrored a cultural reluctance on the part of some patients to learn all the facts even when they suspected a grim prognosis. Since Muslims believe in a divinely predestined time of death, which no human has the power to alter, discussions regarding the duration of remaining life are seen as meaningless.

Religious Beliefs and Concepts of Death

A few governmental and many private health care institutions in the country now offer tertiary level medical and surgical interventions, including open-heart surgery, major joint replacements, in vitro fertilization, and neonatal surgical interventions. Although poverty and lack of third-party payers limit access to private institutions, government-run health services are heavily subsidized and available to the general population. Life-prolonging measures in the event of terminal illnesses are beginning to gain ground, particularly in urbanized parts of the country, through progressive importation of scientific technology and increasing numbers of Western-trained physicians. Despite the secular and scientific nature of medical science, religious beliefs continue to shape how patients and educated families perceive terminal disease and impending death. Death, when it occurs, is generally considered to be through divine ordinance and not necessarily a failure of science. Malpractice suits against physicians and hospitals do occur, but the cases are few and far between due to a legal system that is not conducive to this form of litigation.

There is a strong belief that life is merely one stage of human existence and that death can occur only at a divinely appointed hour. Following physical death, humans are believed to return to God and a spiritual life.²⁹ The focus for a patient and her family when critical illness strikes is often not so much on a fear of death but rather on preparation for the “next” life through worship and prayer. A conversation with the grieving father of a dying five-year-old boy demonstrated to me the role of religious faith in making sense of even the tragic deaths of children. Despite radical surgery and chemotherapy for a renal tumor, the child’s cancer had spread rapidly. The parents had maintained a vigil at their son’s bedside for days as the battle to save his life was slowly lost. With tears in his eyes, the father (a lawyer) told me it seemed that God had ordained just so many days on earth for his son, and expressed his belief that medical science

could never defeat death. Human intellect could not comprehend God's plans or question His will. Thus medical science and technology are accepted as having limits, and death is seen as the will of God.

The conversation among patients, families, and often the most "scientifically" trained physicians is usually peppered with references to the will of Allah and His control of events on earth. While transmitting news of a successfully performed surgical procedure that is expected to have a good outcome, a surgeon will invariably add *inshallah*, "if God wills." A family reporting that the patient is recovering well from an extensive medical intervention will always remember to end this news with *mashallah*, "with the grace of God" or *subhanallah*, "praise be to God."

Hospitals with technology that can extend the life of those who are terminally ill are not yet as widely available in Pakistan as in the industrialized world, and most patients die at home amidst their families. The final hours are spent in prayers and recitation of the Quran, activities in which all members of the extended family and close friends participate. Whether the relentless march of science in prolonging life and postponing death in intensive care units and a greater accessibility of this technology in Pakistan over time will change the prevalent attitude toward life and death remains to be seen.

Economics and Family Decisionmaking

Despite a small affluent sector, in Pakistan the average per capita income is approximately \$430. (The 1997 Encarta lists this figure as \$19,000 for the United States). Health care often not the best is provided free in overcrowded government-run clinics and hospitals, but patients usually pay cash for medications as well as a fee for specialized investigations. There are no third-party payers and few health insurance schemes in the private and public sectors. Private hospitals, with a better standard of care, sometimes maintain a budget for the treatment of the indigent, but primarily run on a system of fee for service.

Poor and middle class family units often consist of three-generation households with one or more breadwinners who pool their resources for the extended family. Familial obligations, particularly to aging parents and the care of several children in the household can have serious financial implications for the family in case of protracted illness of any one member. In his analysis of the decisionmaking process in Japan, Michael Fetters uses the term "family autonomy" to refer to the societal norm for dealing with medical issues.³⁰ In his opinion, although physician paternalism characterizes patient-physician relationships in Japan, the family, particularly the male head of the household, forms the locus for decisionmaking. By necessity, decisions must take into consideration the financial survival of the family rather than preferentially emphasize any one member's rights in isolation. The same is often painfully evident in Pakistan, a much less affluent society than Japan, where there are no public financial aid programs to cover health costs in the case of protracted or life-threatening illnesses. Such situations can be morally troubling and a source of considerable anguish for physicians, who believe that professional and moral obligations to provide medical care should be based on need rather than an ability to pay.

I was faced with such a situation when a three-year-old girl was brought to the emergency room severely dehydrated from prolonged diarrhea that had been refractory to treatment by a general practitioner. Her only chance for survival, I believed, was through admission and parenteral hydration. The grandmother and father accompanying her refused admission, requesting instead a prescription for medications that could be given to her at home. The father was a tailor, the sole breadwinner in a family with six children and two elderly grandparents. Due to a festival later that week he had a large number of requests to stitch clothes and thus an opportunity to earn much needed money. The entire family, including the children, were needed at home to cope with the additional work. Admitting the child to the hospital at this point would not only be an added expense, but would also reduce the manpower for work as one family member would have to stay with the child in the hospital. When I insisted on the admission, the grandmother pointed out to me that while my concern as a physician was for this one child, the family had another five at home who needed food and clothing.

This case presents a stark example of the socioeconomic realities in Pakistan that force families with limited resources to make distressing choices and leave physicians in a moral quandary. The survival of the entire family unit superceding the interest of an individual member is an extreme example of family autonomy and a form of distributive justice at the micro level. In countries with effective social services and government financial aid programs this degree of family autonomy would perhaps not arise. In Pakistan, it remains a daily reality for families and health care professionals.

On another occasion I was asked to consult on a sixteen-year-old boy with Down syndrome who was left a quadriplegic due to cervical spine subluxation. All surgical attempts to stabilize his spine had failed and the progressive and complete paralysis of his respiratory muscles now made him ventilator dependent. He was unable to breathe without mechanical support, but remained awake and fully conscious. Prior to this event he had lived in a remote village with his extended, middle class family composed of twelve people. The family, very fond of their youngest member, had pooled resources to bring the patient to the private, tertiary care, university hospital in the city hoping for a cure. During the subsequent two months of hospitalization, the family sold their only car and part of their land to help defray the cost. They were now not in a position to pay any more. A brother, one of the family breadwinners, had lost his job because he would not leave the patient alone in the unfamiliar surroundings of the hospital. After two months in the hospital, the life of the patient was evidently pitted against the survival of his entire family. Distressed at what he saw as prolonged suffering on the part of the patient, the brother told me that if they had known of this outcome, they would never have brought him to this hospital with its “machines and specialists” and his brother “would have died at home in peace.”

In Pakistan and other developing countries, skilled physicians and surgeons are no longer difficult to find. State of the art technology is beginning to take root in the public and private sectors. The opportunities for prolonging life are on the rise, but there are few support services outside hospitals and the associated increase in health care costs can bring with it devastating financial and emotional burdens for many families. The issue of arriving at a fair distribution of health care services in the face of limited resources is becoming a vexing one for even affluent countries. Recently, it has been suggested by some that in “futile” cases at least (with the admitted difficulty in agreeing on the definition of futility), it may be morally justifiable to give family interests and the issue of distributive justice decisive weight over the interests of the individual.³¹ But the circumstances in impoverished countries like Pakistan can lead to even more intensely troubling dilemmas for physicians. Patients like the two I have described, who do not fit even the broadest definition of “medical” futility, can raise wrenching issues about which is the morally correct choice or indeed, whether a morally correct choice exists at all.

Finding a Middle Ground

In recent years, a narrow focus on patient autonomy has been criticized as being non-contextual and based on an abstract concept that the individual is isolated and disconnected from the many relationships within which he or she actually exists. The Pakistani family-centered model of decisionmaking, in contrast, works on the premise that the family exists in mutually trusting and interdependent relationships that stress caring and love rather than individual rights. When illness strikes, the physician is expected to act as an authority figure who is seldom questioned in the therapeutic arena.

Decisionmaking by the family, if strictly authoritarian, may hold inherent risks for some members of the family unit. In patrilineal families, the norm in many Eastern societies, there can be inadequate representation of the interests and wishes of certain family members, often women, who are economically dependent on the male head of the family or are powerless for other reasons. An unquestioned acceptance by the physician of implicit agreement on the part of such members to every decision that is made on their behalf can carry risks for the most vulnerable family members. This was illustrated in a case that was brought to my attention by a Pakistani surgeon. An elderly woman came with her son, with whom she had

lived for many years, to be scheduled for an elective biopsy of a breast mass. During the meeting with the surgeon, the son mentioned that his mother also had gallstones and requested that a cholecystectomy be done along with the breast biopsy. The patient, who was present during this exchange with the surgeon, did not disagree and accepted without questioning the son's signature for both procedures on her behalf. As a son consenting for the mother is not an unusual occurrence in Pakistan, the surgeon interestingly, also a woman made no attempt to question the patient directly regarding her wish.

Just prior to being administered general anesthesia in the operating room, the patient told the surgeon that she did not wish the cholecystectomy to be done, something she had not verbalized in the presence of her son. Much to the anger of the son when he was informed later, the surgeon complied with the woman's request. The son expressed his concern that it was in the best interest of his mother to have had her gallbladder removed to avoid another anesthetic and surgical procedure in the future. When she shared this episode with me, the surgeon confessed that instead of accepting the common tradition of a male in a family signing the informed consent for female members, she should have probed the patient's own wishes and been sensitive to what might have been fear and anxiety on the patient's part regarding the cholecystectomy.

Although in this case the patient did eventually voice her preference in the absence of her son (perhaps due to the gender of the surgeon), undoubtedly many cases occur in which the concerns and wishes of a competent patient are ignored or overridden in a nonparticipatory process of decisionmaking. An unquestioned, face value acceptance by the physician of cultural norms can jeopardize respect for the individual as a person, a prerequisite for the covenant between a physician and her patient. It is often easier and certainly less time-consuming to take refuge behind a veil of uncritical respect for cultural norms. In societies like Pakistan, physicians can utilize the tremendous respect they command to assess each encounter with a patient and family carefully to strive for a participatory process of decisionmaking, particularly when some members of the unit have been dealt a stronger hand culturally.

With rising literacy rates (albeit slower in women) and greater awareness, in time Pakistani physicians may well face an increase in the number of patients who wish to know more about their illness and prognosis. An automatic assumption that family members must be given the details of the disease while this information is withheld from the patient may become difficult to defend. However, my own experience suggests that in the social context of Pakistan there can be considerable variation in patients' responses to offers of full disclosure of illness. A measure of sensitivity and discrimination is needed in the context of the prevalent, widely accepted societal belief that caring involves shielding one's family members from distressing news.

This was illustrated for me by the case of an intelligent, educated, sixty year-old woman hospitalized with abdominal pain and diagnosed to have a large, unrespectable malignant liver tumor. As is accepted, I gave this news first to her only son, with whom she had lived since the death of her husband a few years previously. He felt strongly that telling his mother she had cancer would depress her and make her "lose hope." He felt she should be told that she had a liver "infection." He added that since her husband's death, she had always relied on him for all major decisions. Conceding that he knew his mother better than I did, I told him that as his older sister a kinship he had bestowed on me I felt it was important to judge first whether his mother would indeed not wish to know a diagnosis that carried major implications for her. After a while we reached a compromise: I would not use the word cancer but would tell her she had a large "tumor," but I would not lie to her if she asked me a direct question regarding the nature of the tumor, including whether it was malignant. The son assured me that she would not and he was right. During several conversations with the patient in which we talked about her "tumor," despite several openings I offered her, she never once questioned me about what kind of tumor it was or whether this would affect the duration of time she had left to live information I had been certain she would wish to obtain. On the other hand, I have come across other patients over the years who have not only asked

questions of varying depth, but have also indicated their preferences in decisions regarding their medical care.

A shift away from an authoritarian family decisionmaking process is possible, but the physician must use discrimination, judging encounters with each patient and family on their own merit. With appropriate rapport with the family and sensitivity to the wishes of a particular patient, cultural norms can be challenged. In Pakistan, the physician as a matriarch can also work toward neutralizing some of the unfair leverage that one family member may have over another in the decisionmaking process. A young couple brought their infant to me with a nonfunctioning kidney that needed to be excised. When the time came to discuss the surgery, the husband asked the wife to take the child out to another room to feed her. He then requested that I give him the details of the nephrectomy but tell his wife only that a “biopsy” was needed. He was concerned that she was too tender hearted to stand the shock of being told that the kidney would have to be removed and he did not wish to upset her. As I had already been inducted into the position of mother by the young man, I informed him that mothers had the right to decide themselves how much they wished to know about the medical plans for their children. The anxious woman was called back into the room and, on my questioning, expressed a wish to be told exactly what surgery was needed for the child. As I proceeded to do so in my role as the “wise” matriarch, the husband’s apprehension gradually subsided.

Deeply entrenched religious beliefs and cultural norms that emphasize the primacy of the family and well defined roles within it are realities in Pakistan. I believe that replacing a system of supportive interdependent relationships within families with another that focuses on disconnected individual rights exclusive of family interests is neither feasible nor desirable. However, a shift to some kind of middle ground is necessary. This can be facilitated if physicians play a role befitting a Hakim, bestowed on them through long-held cultural and religious traditions. As my own experience illustrates, there is room for flexibility between a rights-based, patient-centered model of decisionmaking and another in which the identity of the patient and individual members may be lost in the collective consciousness of the family unit. A dynamic balance can be found that preserves important cultural values of duty and caring within families and introduces a possibility for individual members to participate in their own medical decisions. In Pakistan the physician, with her unique standing in society, is ideally suited to serve as the catalyst to begin a move toward such a middle ground.

This being said, the other risk to patients in Pakistan ironically comes from the physician herself. It lies in the potential for abuse of this unchallenged power that physicians command in a country where the population is largely illiterate and economically disadvantaged. Unquestioned authority of the medical profession and a fatalistic belief among the population regarding illness and death can leave patients open to exploitation by unscrupulous physicians. I am aware of instances in which improper care or medical negligence was camouflaged by references to divine predestination leading to the death of a patient. Institutional and organizational checks and balances of physicians and the medical profession as a whole are variable in effectiveness even in many institutions where they exist. Furthermore, there is a general lack of awareness of individual rights and redress through the judicial system, which is not accessible to most. All these factors combine to leave patients and their families exposed to exploitation by health care professionals.

In religious societies like Pakistan, physicians have been expected traditionally to draw their professional morality from duties and obligations. But times are changing. The medical education of physicians for some years now has been occurring in a secular, scientific milieu, and Pakistani physicians are no exception. According to Fazlur Rahman, a professor of Islamic thought at the University of Chicago, the medical tradition in Muslim societies is losing “the warmth of the cultural home in spiritual terms.”¹⁴ With the progressive shift to medical specialization and increased use of impersonal technology, all with undoubted benefits, physicians in Pakistan are moving away from close relationships with patients and

their families to an approach that is distant and akin to the contractual model prevalent in the West. Such relationships require an informed, literate population and a society with well-established, effective checks and balances through institutional, professional, and governmental bodies. If these are absent or do not function well, patients and their families have little recourse against exploitation. In the Pakistani context at least, within the family-physician-patient triad it is the physician who can be the most influential in working toward a model that respects a cultural tradition of family caring yet draws the patient into the decisionmaking process.

References

1. T.L. Beauchamp and J.L. Childress, *Principles of Biomedical Ethics*, 4th ed. (New York: Oxford University Press, 1994).
2. G.J. Annas, "The Health Care Proxy and the Living Will," *NEJM* 324 (1991):1210-13.
3. R.S. Dresser and J.A. Robertson, "Quality of Life and Nontreatment Decisions for Incompetent Patients," *Law, Medicine and Health Care* 17 (1989): 234-44; N.K. Rhoden, "Litigating Life and Death," *Harvard Law Review* 102 (1988): 375-446.
4. J.A. Carrese and L.A. Rhodes, "Western Bioethics on the Navajo Reservation," *JAMA* 274 (1995): 826-29.
5. L. Blackhall et al., "Ethnicity and Attitudes towards Patient Autonomy," *JAMA* 274, no. 10 (1995): 820-25.
6. H.L. Nelson and J.L. Nelson, "Family," in *Encyclopedia of Bioethics*, ed. W.T. Reich, rev. ed. (New York: Simon and Schuster MacMillan, 1995), pp. 801-808; M.G. Kuczewski, "Reconceiving the Family: The Process of Consent in Medical Decisionmaking," *Hastings Center Report* 26, no. 2 (1996): 30-37; J. Hardwig, "What about the Family?" *Hastings Center Report* 20, no. 2 (1990): 5-10; J.L. Nelson, "Critical Interests and Sources of Familial Decision-Making Authority for Incapacitated Patients," *Journal of Law, Medicine and Ethics* 23 (1995): 143-48.
7. J. Areen, "Advance Directives under State Law and Judicial Decisions," *Law, Medicine and Health Care* 19 (1991): 91- 100.
8. A. Kleinman, "Anthropology of Medicine," in *Encyclopedia of Bioethics*, ed. W.T. Reich, rev. ed. (New York: Simon and Schuster MacMillan,), pp. 1667-73.
9. F. Rahman, *Health and Medicine in the Islamic Tradition* (Chicago: ABC International Group, 1998), pp. 1-3.
10. R. Patel, *Islamization of Laws in Pakistan* (Karachi: Saad Publications, 1986), p. 9.
11. J. English, "What Do Grown Children Owe Their Parents?" in *Having Children: Philosophical and Legal Reflections on Parenthood*, ed. O. O'Neill and W. Ruddick (New York: Oxford University Press, 1979), pp. 351-56.
12. See ref. 6, Kuczewski, "Reconceiving the Family."
13. Quran, Chapter 17, Verse 23: "Your Lord has commanded that you worship none but Him, and do good to your parents. If either or both of them attain old age in your company, show them no impatience, but speak to them kind words. Lower to them the wing of humility"; Chapter 4, Verse 36: "To everyone we have appointed heirs of that which parents and kinsmen leave. So give to them their share."
14. See ref. 9, Raman, "Health and Medicine in the Islamic Tradition" p. 30-31.
15. J. Blustein, "The Family in Medical Decisionmaking," *Hastings Center Report* 23, no. 3 (1993): 6-13.
16. R.M. Zaman, "Psychotherapy in the Third World: Some Impressions from Pakistan," in *Psychology in Internal Perspective*, ed. U.P. Gielen, L.L. Adler, N.A. Milgram (Amsterdam: Swets and Zeitlinger, 1992), pp. 314-20.
17. M. Fetters, "The Family in Medical Decision Making: Japanese Perspectives," *Journal of Clinical Ethics* 9 (1998): 132-46; P.J.L. Donnelly, "The Impact of Culture on Psychotherapy: Korean Clients' Expectations in Psychotherapy," *Journal of the New York State Nurses Association* 23 (1993): 12- 15; T.M. McIntyre, "Family Therapy in Portugal and the U.S.: A Culturally Sensitive Approach," in *International Approaches to Family and Family Therapy*, ed. U.P. Gielen and A.L. Comunian (Padua: CDEM, 1997), pp. 1-51; R.M.

- Zaman, "The Adaptation of Western Psychotherapeutic Methods to Muslim Societies," *World Psychology* 3 (1997): 65-87.
18. See ref. 17, Zaman, "The Adaptation of Western Psychotherapeutic Methods."
 19. See ref. 17, Fetters, "The Family in Medical Decision Making."
 20. See ref. 11, English, "What Do Grown Children Owe Their Parents?"
 21. F. Rahman, "Islam and Medicine," *Perspectives in Biology and Medicine* 27 (1984): 585-97.
 22. H. Hathout, *Topics in Islamic Medicine* (Kuwait: Publications of Islamic Medicine Organization, 1983).
 23. First International Conference on Islamic Medicine, *Islamic Code of Medical Ethics*, Kuwait Documentary, Kuwait Rabi 1, January 1981.
 24. See ref. 22, Hathout, "Topics in Islamic Medicine"; ref. 23, First International Conference, *Islamic Code of Medical Ethics*.
 25. Quran, Chapter 5, Verse 32: "Whosoever takes a life, except to combat murder and villainy on earth, it is as if he killed all mankind."
 26. M.A.S. Abdel Haleem, "Medical Ethics in Islam," In *Choices and Decisions in Health Care*, ed. A. Grubb (London: John Wiley and Sons Ltd., 1993), pp. 1-20.
 27. J.C. Holland, N. Geary, A. Marchum, S. Tross, "An International Survey of Physicians' Attitudes and Practice in Regard to Revealing the Diagnosis of Cancer," *Cancer Investigation* 5 (1987): 151-54.
 28. See ref. 4, Carrese and Rhodes, "Western Bioethics on the Navajo Reservation."
 29. Quran, Chapter 16, Verse 6:1 "When their term is come, they would not put it back by a single hour, nor put it forward"; Chapter 2, Verse 28: "He gave you life, then He shall make you dead, then He shall give you life, then unto Him you shall be returned."
 30. See ref. 17, Fetters, "The Family in Medical Decision Making."
 31. D.W. Brock, "What is the Moral Authority of Family Members to Act as Surrogates for Incapacitated Patients?" *Millbank Quarterly*.

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Informed Consent in the Pakistani Milieu: The Physician's Perspective

A. M. Jafarey, A. Farooqui

Abstract

Informed consent enjoys an unassailable position in both clinical and research situations as a safeguard of patients' rights. Keeping the patient involved in the decision making process is easier when there is direct communication with the individual. The Pakistani milieu offers challenges to this process because crucial decision making is often done by family members or is left entirely up to the attending physician. There seems to be a general acceptance of this shifting of focus from the individual to other players. This also raises certain ethical dilemmas for physicians who may feel uncomfortable with communication which excludes the patient or in accepting a paternalistic primary decision making role. The objective of this informal qualitative study was to ascertain physicians' perceptions regarding the process of information delivery to the patient in the Pakistani context and the various influences acting upon it.

Introduction

The stipulation that an individual be fully conversant with all the relevant facts is central to the concept of informed voluntary consent both in research and clinical situations.¹ Only then can the process of informed consent play the role of a safeguard that upholds autonomy and acknowledges the fundamental position of the individual's choice.² Centrality of the individual in the medical decision making process is sacrosanct in the West with the patient actively involved in all discussions with the physicians.³ The importance of individual autonomy however is challenged in many Eastern cultures.⁴ In the Pakistani context, there are several other factors to consider in crucial decision making situations. In some cases, the patient opts to exclude himself from receiving information and participating in discussions regarding his management, delegating family members to make the decisions. Alternatively he may invite his physician to use his best judgment and choose the best option for him. In other situations, the family members may insist on excluding the patient from the decision making loop. This family, physician, and patient triad in Pakistani society in medical decision making has been comprehensively documented by Moazam.⁵ A tradition of living in extended families, often with shared incomes, strengthens the role of the family in major decision making situations like selection of marriage partners, financial transactions, and in making decisions about medical treatment.

Requests from patients like "Doctor Sahib, you are like my elder sibling or parent. You know what is best you decide for me" are not uncommon in this part of the world. How should the physician proceed when the onus of decision making is thrust upon his shoulders? Should he accept the imposed paternalistic role and proceed according to his own best judgment, respecting the patient's right to exercise autonomy and decision not to know? Or should he still insist on involving the patient? Is the physician, in performing his "duty" to convey information to the patient irrespective of the patient's desire actually respecting the patient's autonomy?⁶

In another common scenario, a family member may take the physician aside and ask him to carry on with his management but not to tell the patient that she has a life threatening disease as she is “faint of heart” or would not be able to “sustain the shock”. Here again the physician faces the conflict between upholding the patient’s right to know and respecting the desire of the family to shield the patient from bad news.

This change of focus from the individual to the family or the physician raises the question of the role of individual autonomy in this culture and the whole concept of informed consent. Who needs to be informed and who will participate in making the decisions? The apparently different set of ground rules gives rise to numerous ethically challenging situations in clinical practice in Pakistan.

There is paucity of information regarding the various factors affecting the process of information delivery and medical decision making in Pakistan and the importance of the different key players influencing the process. This informal qualitative study was designed to gain deeper insight into physicians’ perspectives regarding this process. The objective was to evaluate how physicians at this institution approach such situations in their clinical practice. What are their guiding principles in the process of informing the patient about his disease, its prognosis, and treatment? We also explored the impediments they face in the process and ascertained the level of satisfaction with their practice in this regard.

Methods

This informal qualitative study was conducted at Aga Khan University Hospital, Karachi, Pakistan, and a private sector tertiary care hospital. Three approaches were used which included focus group discussions, individual in-depth interviews, and informal discussions to gather data. The perceptions about informed consent from various levels of physicians including professors, associate professors, assistant professors, senior instructors, fellows, and chief residents were obtained. These physicians were from specialties including surgery and allied fields, gastroenterology, oncology, rheumatology, family medicine, cardiology, neurology, and invasive radiology.

The commonality among the various specialties listed above was based on their interaction with patients and frequent need for passage of information from them to the patients. Their diversity lies in the different kinds of diseases they deal and the various modes of interventional and non-interventional treatments they apply in the dispensation of healthcare.

A facilitator introduced the topic to the participants of the focus group discussion and put forward non-leading questions to highlight the issue being discussed. In each focus group 10–12 physicians from various specialties participated in the discussion. In order not to influence the proceedings, the facilitator did not participate in the discussion. Comments were recorded and simultaneous notes were also taken. These were immediately transcribed and authenticated by both the authors. The transcribed material was then analyzed for identifying the various responses from each group and then grouped accordingly in the result. We stopped after the fifth focus group discussion because of overlapping information.

Seven key informants who had not participated in the focus group discussions or the informal discussions were identified from major specialties. Verbal consent was taken from each participant. The facilitator used the informal free conversational approach for the interviews, the main aim being to obtain personal experiences that would further expand on the perspective. These interviews were transcribed immediately after the meeting and the transcriptions individually analyzed for identification of the key points.

Five informal interviews were carried out on the basis of convenience sampling. Physicians who were available for the interview were requested to participate in the exercise in an informal manner. A verbal

consent was also obtained from them before the interview. These interviews were also transcribed immediately after the meeting. Again the transcriptions from each individual were analyzed for key points.

Results

The discussions were focused in the area of information delivery in the process of informed consent and the roles played by the various key participants. Apprehensions regarding the various pitfalls inherent to this process in our society were also debated. The physicians also talked about the extent of their moral satisfaction with the process of information transfer as practiced at present and suggestions for improvement were put forward, keeping in mind cultural and social values.

Information

Most participants felt that it was the physician's duty to bring the patient into the decision making process. The prevailing opinion across the different focus groups was that regardless of the opinion of the patient or the family, the physician is obligated to deliver at least some basic information to the patient. It was a general opinion that information about the disease and the treatment ensures participation and helps the patient respond better to the management. The patient could therefore not absolve himself from his right to know what was happening to him and nor could the family take away this right from him.

There was wide divergence of view regarding the extent of information to be provided, from giving encyclopedic levels of information to outright deception. The majority felt that the process needs to be individualized, and a tiered approach was suggested, starting from the basic facts and going further based on the patient's demands. Some participants emphasized outlining the risks versus the benefits of a particular therapy to the patient. There was no consensus on how to identify essential information from the "details" that could be omitted.

The issue of voluntarily withholding information came up repeatedly in the discussions. Most participants agreed that it was perfectly acceptable to use alternative words like 'growth' or 'mass' rather than use the term "cancer" and this did not amount to deception. The general view was that the patients usually already knew or suspected strongly what was wrong with them, especially patients with malignancies.

Some of the physicians were comfortable with entirely excluding the "more distressing" facts about their disease or giving a more "optimistic" picture to the patient. Physicians as opposed to surgeons were more comfortable in withholding the exact diagnosis if they felt that revealing all the facts could enhance the distress of the patient and not contribute meaningfully towards the management. "You can be evasive regarding the diagnosis if the patient does not ask you directly" said one physician. This group however was of the firm opinion that if a procedure has to be undertaken, it has to be explained to the patient even if the family says otherwise. This was necessary to ensure the patients cooperation for the procedure.

Role of the Family

When a family member is taken ill, it is common to see several family members accompanying the patient to the doctors' office and if a patient is admitted for treatment, one can often see several family members camping outside in the open for days. "Not only does the patient bring his family along when he comes to visit the doctor, at times it seems he has brought along the entire family tree!" remarked one participant.

"There is no difference between the patient as an individual and his family. Both are one and the same."

All participants accepted the key position enjoyed by the family in decision making processes in Pakistan. Many of the participants refused to draw a distinction between the patient and the family in this culture,

claiming that they are inseparable and should be addressed as a one unit. “There is no difference between the patient as an individual and his family. Both are one and the same” said one physician. Several participants pointed out that the doctor first confronts the family members with the diagnosis, especially when suspecting cancer, before approaching the patient. Often a joint strategy is hurriedly arrived at between the physician and the family before approaching the patient. The question asked by many was “how then can the role of the family be relegated to anywhere below that of the patient himself?”

Apprehensions

Several participants voiced their apprehensions in following a Western oriented blind information delivery policy without considering the wishes of the patient and the family. One fear of spelling out details of the diagnosis, the prognosis, and possible complications of procedures was of scaring the patients away to other practitioners with a more reassuring “trust me, you will be fine” approach. Losing patients translates into losing valuable experience and revenue and is a tightrope that needs to be walked at times. As one relatively junior surgeon said, “I try and tell the patient all possible complications of a procedure so that if something does go wrong, at least he was forewarned. I however, tend to lose patients also by this approach as they sometimes choose to go to a surgeon who does not alarm them with all the possibilities”. This candidly expressed fear of losing patients by providing too honest an informed consent may tempt physicians to “recruit” patients by giving a rosy “nothing will go wrong” picture. This appeared to be more of an issue for the relatively junior staff still in the formative stages of their practices and it came up several times in the discussions.

A concern that was voiced repeatedly was whether we as physicians were imposing ‘foreign’ values on the patients by thrusting upon them unwanted and unsolicited autonomy. Participants felt that they were unclear about the importance and the relevance of autonomy for the end user the patient and in dragging them into the decision making process we may actually be harming them in an unintended way. “The job of a doctor is to reassure and comfort the sick, not to frighten them” said one surgeon, quoting a patient.

Although physicians were generally willing to let the physician-patient-family balance remain undisturbed, a concern was voiced regarding the legality of making decisions in consultation with the family even if it was done at the insistence of the patient himself. It was pointed out that in the event of a complication there was nothing stopping the patient from turning around and saying that he was not made aware of the choices before the operation and then proceeding with litigation. Some participants felt that there was no mechanism in place to capture the dialogue between all concerned parties that went into the process of informing the patient, assessing his understanding, and getting his permission.

Factors Adversely Affecting the Process

Several factors came across as having an adverse effect on the process of informed consent. One such issue was time: process of obtaining a truly informed and understood consent requires time and patience, both deficient in busy clinical practices. A tiered process (as advocated above) requires that the understanding of the patient be gradually built up and comprehension verified to an extent that satisfies both parties. In busy practices this becomes more and more difficult. As one surgeon said, “I am quite satisfied with my interaction with the patient regarding the informed consent process right now but I am not sure if this would remain so as my practice gets busier.”

One fact that kept coming up was the influence of the level of intelligence of the patient on the quality of the interaction. There seemed to be an obvious hesitation on the part of the participants in equating the lack of intelligence with an inability to comprehend what was being told. Participants were however much more comfortable in saying that a higher level of intelligence did facilitate communication. It was emphatically added that a perceived lack of intelligence should not be a reason not to communicate. A common statement was “every effort should be made to come down to the level of the patient in order to explain the facts.”

Another area that raised forceful objections was in equating education with intelligence. Participants were generally of the view that both could not be equated and an uneducated person could be intelligent and vice versa. But a lack of education was also pointed out as a hindrance in satisfactory communication and again participants emphasized the need for more effort to get the message across to an uneducated patient.

A physician pointed out that the female sex carries with it its own issues in this society. In obstetrics practice for instance, women may be unwilling to acknowledge any information given to them or sign a consent document unless they have their husbands present. They may even be happier leaving the discussion entirely to their spouses, willingly assuming a back seat in the decision making process concerning their own health.

“I take ten minutes to tell the interpreter what is wrong with the patient and he takes inside of a minute to talk to the patient and obtain the thumb imprint.”

Another important factor for the hospital at which this study was conducted was that of consent through interpreters. Afghan refugees with no knowledge of the local languages or English constitute a significant proportion of patients in this hospital. Apart from one surgeon who had learnt enough Persian to get by, all other doctors used the volunteer interpreter service. None of the physicians were entirely satisfied with the use of the non-professional interpreters and, although they were fulfilling the legality by obtaining the signature or thumb imprint on the dotted line, they were dissatisfied by the quality of information delivered. “I take ten minutes to tell the interpreter what is wrong with the patient and he takes inside of a minute to talk to the patient and obtain the thumb imprint” said one doctor. Physicians had devised ways of getting around this problem like making the interpreter translate one sentence at a time to make sure all the facts were delivered. All voiced a desire to have a professional service of trained interpreters who know the importance of conveying the information correctly, checking comprehension and then carrying out the legal formalities.

Satisfaction with the Process

The level of satisfaction of the physicians with the information delivery process depended primarily upon the achievement of two criteria: delivering information to the patient and assessing comprehension. Those physicians whose practices allowed them to spend more time with the patients were more satisfied than those with busier practices. Experience in dealing with a variety of patients and families also made a difference.

One factor that helped physicians do the job better was interaction with a well-informed patient. Cardiac patients for instance, referred to a cardiologist for angiographies, were found to be generally well informed of their disease and the various options available. It was therefore easier to communicate with them and satisfactorily agree on a plan. It was stressed that publicity or educational material like brochures describing a procedure also appeared to facilitate the process for the physicians.

Physicians who do a specific variety of invasive procedures such as gastroenterologists and cardiologists, invasive radiologists, or physicians who see only a certain variety of patients, like oncology patients, were generally more satisfied by the process of informed consent. They had devised their own mental checklists of “must tell” points to the patients and as long as they used them, they were content. In fact, the only person “absolutely” satisfied by his practice of informing the patients of their disease, its prognosis, and the plan of therapy was an oncologist: “There are six things that a patient must know before commencing chemotherapy. I make sure they understand them and then I proceed.” Some physicians advocated the development of checklist type consent forms for major procedures in all fields. Even if it meant the form to be spread over several pages, all the important agreed upon points would be covered. The participants most unsatisfied with the process of information delivery were the surgeons.

Perhaps a wider variety of pathology that they see prevents them from devising these mental pathways for each patient.

Comments and Conclusions

The consent process has two distinct but not necessarily incompatible objectives. It acts as a tool to minimize chances of legal action resulting from a complication of therapy by providing prior information regarding the possible eventualities and getting the patient's agreement before proceeding further. It also emphasizes the moral responsibility of the physician in acknowledging the autonomy of the patient and ensuring his inclusion in the decision making process. Completing one component does not necessarily imply that the requirements for the other have also been fulfilled.⁷ These sentiments were echoed by the participants in our study who felt that the consent form was a mere legality and its completion did not signify the conclusion of the moral responsibility of the physician in keeping the patient informed.

The recommended method for obtaining an informed consent in this hospital requires the consultant to have a detailed discussion regarding the various aspects of the recommended procedure with the patient at the time of booking for the procedure. The patient is asked to sign a printed consent form available in Urdu and English if he agrees with the plan. This exchange usually takes place in the out patients' clinic before admission for the procedure. Although the paperwork is taken care of, the patient obviously has the right to retract consent at any time. This delay from the time of signing the consent until the actual procedure enables the patient to have sufficient time to discuss and reflect on his decision, and he has the option of contacting the physician again for further clarification.

There was unanimity regarding the importance of delivering information to the patient regarding major aspects of the treatment and bringing him into the decision making loop. There has been an increasing trend over the past three or four decades towards more disclosure, even in cultures where physician paternalism is traditionally well accepted like Japan, and Eastern and Southern Europe.⁸ Even in the US where personal autonomy has always been of overriding importance, physicians were much less likely to disclose the diagnosis of cancer to their patients in the early 1960s than they were by the end of the seventies.⁹

There was considerable lack of clarity regarding the extent of information considered adequate. Some physicians felt there was a place for evasiveness as far as disclosure of the diagnosis was concerned if it protected the patient from additional distress. The respect enjoyed by the physician in our society imposes certain moral responsibilities on them, one being the balanced presentation of facts which neither unduly alarm nor entice patients but facilitate decision making.

The quality of consent was clearly equated with the amount of time spent and the experience of the physician. Most physicians felt that lack of intelligence or illiteracy influenced comprehension negatively but could be overcome by spending more time in imparting information. Following checklists was found by some physicians to be an efficient way of delivering information, especially for routine procedures, and there were suggestions to consider devising checklist type of consent documents for all commonly performed procedures.

Most physicians also acknowledge the family and the patient as inseparable entities in this society and found it morally acceptable to include the family in the decision making process along with the patient. "In Pakistan, for the vast majority of the population, you are your family, and the family is you."⁵ One way of officially endorsing the role of the family in the informed consent process is to identify a next of kin formally on the consent form as a legal representative of the patient. This could remove inhibitions that some physicians experienced in communicating "through" a family member rather than with the patient directly. With a legally identified and duly authorized next of kin the fear of litigation would also be eliminated.

An apprehension repeatedly surfacing was that physicians were basing practices on what they personally considered to be appropriate values. In the words of one surgeon, “The physician has the best interest of the patient in mind and it is in the best interest of the patient to know about the disease.” This paternalistic sentiment was echoed by others also. This viewpoint may not necessarily be shared by the patients. Are we attempting to respect the patient’s autonomy without actually knowing whether the patient understands the autonomy that we are insisting on upholding?

This study has brought out several areas of concern in the moral aspects of the existing informed consent process and a few practical suggestions have also emerged. A lacuna in our understanding that has been identified is in the area of patients’ values regarding autonomy and their opinion concerning the role of the various players in the process of informed consent. Another area that remained untouched in the discussions undertaken for this study is the teachings of Islam regarding individual rights and caregivers’ responsibilities.

Any attempt to gain a deeper insight into the role of the individual, family, and the physician in medical decision making in the Pakistani context will remain incomplete without going into the teachings of Islam in this respect. It is also imperative that the patient’s opinions regarding the role of the various influences acting upon the process are also taken into account so that policies and practices can be based on locally acceptable facts and not on imported ideals. These could be areas of further research in order to unravel the patient, family, and physician triad in the Pakistani society.

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References

1. Beauchamp TL, Childress JF. *The Principles of Biomedical Ethics*, 4th edition. New York: Oxford University Press, 2001.
2. Joseph AC, Lorna AR. Western bioethics on the Navajo reservation: benefit or harm? *JAMA* 1995; 274:826–9.
3. Leslie JB, Sheila TM, Gelya F, et al. Ethnicity and attitudes toward patient autonomy. *JAMA* 1995; 274:820–5.
4. Kerry WB, Edwin CH. Bioethics for clinicians: 20. Chinese bioethics. *Can Med Assoc J* 2000; 163:1481–5.
5. Moazam F. Family, patient and physician in medical decision making: a Pakistani perspective. *Hastings Cent Rep* 2000; 6:28–37.
6. Correia JC. Autonomy and identity. *J Med Ethics* 2000; 26:141.
7. Lantos J. Informed Consent. The whole truth for the patient? *Cancer* 1993; 72(Suppl 9):2811–15.
8. Horikawa N, Yamazaki T, Sagawa M, et al. Changes in disclosure of information to cancer patients in a general hospital in Japan. *Gen Hosp Psychiatry* 2000; 22:37–42.
9. Novach DH, Plumer R, Smith RL, et al. Changes in physicians' attitudes toward telling the cancer patient. *JAMA*, 241:897–900.

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Syed Mamun Mahmud, "Informed consent needs information,"

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Informed consent needs information

Syed Mamun Mahmud

Benign prostatic hyperplasia (BPH) is a pathology seen in middle aged or elderly males and can present with painful acute urinary retention warranting immediate relief through per urethral insertion of a Foleys Catheter.¹ Transurethral Resection of Prostate (TURP) is considered the gold standard for the surgical treatment of BPH.² TURP is one of the most commonly performed procedures in urology.

A 58 year old male patient presented in the emergency room of our hospital in Karachi with acute urinary retention. He had been passing urine comfortably until a few days earlier. Per urethral catheterisation had been attempted at a small town some three to four hours' drive from Karachi. However, catheterisation had failed and the patient was disposed with an 18 G I/V cannula placed percutaneously in the suprapubic region to drain the urinary bladder. At our centre, the suprapubic cannula was replaced by a 16 Fr suprapubic catheter.

I learned that the patient had undergone TURP five years earlier at another centre and was unhappy about the minimally invasive approach adopted by the surgeon. I explained that the retention was most likely secondary to "re-growth of prostate" or urethral stricture³ and added that the risk of repeat prostatectomy is around 5% in one year, 10-12 % in five years and 20% in 8-10 years.⁴ further explained that although the incidence of repeat prostatectomy is higher with TURP than open prostatectomy, the latter has higher morbidity and costs. The patient who was now comfortable laughed and said, in Urdu, "Doctor Sahib, for me these figures stood out as 100%. Open surgery was suitable for me, because in case of blockage in passing urine it takes very long from Khuzdar to Karachi. Had I been treated with open surgery, I would not have to go through a repeat operation on my gland."

It is difficult to comment on the appropriateness of surgery in this case. Certainly decision making in such a scenario is complex. Still, it is necessary to point out the importance of obtaining truly informed consent.

An ethically valid informed consent has seven necessary elements: a "capable decision maker" (the patient), the patient's voluntariness, disclosure, recommendation, understanding, decision and authorisation. In practice, however, informed decision making is often incomplete.⁵ In one study, just 9% of decisions met "quite reasonable criteria." The understanding of the patient is least frequently assessed (1.5%) and uncertainties and alternatives to the proposed plan of management are rarely discussed.⁶

Patients need to be given the information they need to make decisions. This includes explaining the prognosis, treatment options, and possible complications. International guidelines are relevant but their application is not enough. Nor will sensitivity to cultural and social values suffice for decision making. Decision making goes through a complex process of interaction between the physician and patients or physician, patient and patient's family depending on the nature of the illness and the patient's socioeconomic background and cultural values. So, while suggesting options, the physician needs to be patient centered, elaborating on issues which may be important to a particular patient. They should

consider issues such as basic healthcare access, availability of transportation and also look for ways to overcome such problems within the patient's means.

In this case, the surgeon followed international recommendations but the patient was not mentally prepared for the possibility of re-growth of the gland and retention of urine. Nor was he informed that in case of symptoms of urinary retention, he should visit the nearest hospital early rather than in an emergency. He should also have been told about the option of open surgery and the reason that international recommendations were against it.

The process of acquiring informed consent is complex. It is not always possible to resolve conflicts in decision making, in this case weighing international recommendations versus the patient's desire based on his conditions and socio-cultural issues. But what is important is that the physician shows sensitivity to patients' choices and wishes and their cultural values.

References

1. Semmens JB, Wisniewski ZS, Bass AJ, Holmann CD, Rouse IL. Trends in repeat prostatectomy after surgery for benign prostate disease: application of record linkage to healthcare outcomes. *BJU Int.* 1999 Dec; 84(9):972-5.
2. Fitzpatrick JM, Mebust WK. Minimally invasive and endoscopic management of benign prostatic hyperplasia. In: Walsh PC, Retik AB, Vaughan ED Jr, Wein AJ editors. *Campbells Urology*. 8th edition. Philadelphia: WB Saunders; 2002: 1379-422.
3. Varkarakis J, Bartsch G, Horninger W. Long-term morbidity and mortality of transurethral prostatectomy: a 10 year follow up. *Prostate*. 2004 Feb 15; 58(3):248-51.
4. Stephenson WP, Chute CG, Guess HA, Schwartz S, Lieber M. Incidence and outcome of surgery for benign prostatic hyperplasia among residents of Rochester, Minnesota:1980-87. A population-based study. *Urology*. 1991; 38(1 Suppl): 32-42.
5. Boyle RJ. The process of informed consent, In: Fletcher JC, Spencer EM, Lombardo PA. *Fletcher's Introduction to Clinical Ethics*. 3rd ed. Hagerstown, Maryland: University Publishing Group; 2005:139-56.
6. Braddock CH, Edwards KA, Hasenberq NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA*. 1999 Dec 22-29; 282(24):2313-20.

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Useful Links

1. Farhat Moazam, "Doing bioethics in Pakistan," Hastings Bioethics Forum, *The Hasting Centre Report*, (2012).
2. Farhat Moazam, Riffat M. Zaman, "At the interface of cultures," *Journal of Clinical Ethics*, vol.14, no. 4 (2003): 246-258.
3. Farhat Moazam, "Families, patients, and physicians in medical decision making: a Pakistani perspective," *Hastings Center Report*, vol. 30, no. 6 (2000): 28-37.
4. Aamir Jafarey, Farhat Moazam, "Informed consent is a moral imperative," *Indian Journal of Medical Ethics*, vol. 7, no. 2 (2010).

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Clinical Ethics
2.2: Privacy and Confidentiality
2.3: Truth Telling

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Case for Discussion

A 22 year old patient, while under care of a psychiatrist, confides to him of his desire to kill a class fellow because she refuses to get friendly with him. The psychiatrist continues in his treatment with counseling and medication, but does not tell the university authorities about his patient's homicidal ideation. The psychiatrist believes it would be a breach of confidentiality and he would lose the trust of this patient which would affect the progress made with the care of the patient.

A week later the patient kills his class fellow and her parents sue the psychiatrist.

Did the psychiatrist do the right thing in maintaining the confidentiality of his patient?

How would you have acted in this situation?

Teaching Videos

1 – Privacy and Confidentiality:

- Walking a tight rope. (<https://vimeo.com/109992685>)

The stories depicted in this short video contrast the value of advocating for the patient's welfare against legal and institutional compulsions, when the two may be diametrically opposing forces. The video highlights the tensions healthcare providers face while trying to find a balance between the two.

2 – Truth Telling:

- To Tell or Not to Tell. (<https://vimeo.com/51892379>)

This movie explores issues related to family dynamics and informed consent when a patient's family wishes to shield him from the harsh reality of his ailment and treatment. It portrays tensions between a physician's duty to disclose illness and an individual's autonomy and right to know, versus the love and protective feelings of his children.

Useful Links

- Tom L. Beauchamp and James F. Childress, "Professional-Patient relationships," *Principles of Biomedical Ethics*, Oxford University Press, (2001): 283-336.
- Evan G. DeRenzo, "Privacy and confidentiality," *Fletcher's Introduction to Clinical Ethics*, Maryland: University Publishing Group Inc. (2005): 87-97.
- Clarissa de Pentheny, Catherine Urch O'Kelly, Edwina A. Brown, "The impact of culture and religion on truth telling at the end of life," *Nephrology Dialysis Transplantation*, vol. 26, no. 12 (2011): 3838-3842.
- Shekhawat Laxmi, Joad Anjum Khan, "Does the cancer patient want to know? Results from a study in an Indian tertiary cancer center," *South Asian Journal of Cancer*, vol. 2, no. 2 (2013): 57. http://journal.sajc.org/temp/SouthAsianJcancer2257-832886_230808.pdf.
- Farzaneh Zahedi, "The challenge of truth telling across cultures: a case study," *Journal of Medical Ethics and History of Medicine*, vol. 4 (2011): 11. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3713926/pdf/jmehm-4-11.pdf>.
- Von Kanel, Robert L, "Confidentiality-An analysis of the issue," *Plastic Surgical Nursing*, vol. 17, no. 3 (1997): 146-56.
- Irving Louis Horowitz, "Privacy, publicity and security: the American context," *EMBO Reports*, vol. 7, no. 1S (2006): S40-S44.
- Christopher M. Burkle, Gregory D. Cascino, "Medicine and the media: Balancing the public's right to know with the privacy of the patient," *Mayo Clinic Proceedings*, vol. 86, no. 12. Mayo Foundation for Medical Education and Research, 2011. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3228620/pdf/mayoclinproc_86_12_011.pdf.
- Tomer Simon, Avishay Goldberg, Bruria Adini, "Are ethical norms and current policies still relevant in face of the recent mass terror events?" *Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine*, vol. 24, no. 1 (2016): 118. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5050612/pdf/13049_2016_Article_304.pdf.
- Angus H. Ferguson, "The role of history in debates regarding the boundaries of medical confidentiality and privacy," *Journal of Medical Law and Ethics*, vol. 3, no. 1-2 (2015): 65. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4751619/pdf/emss-66787.pdf>.
- Anant Bhan, "Should health professionals allow reporters inside hospitals and clinics at times of natural disasters?" *PLoS Med*, vol. 2, no. 6 (2005): e177. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1160582/pdf/pmed.0020177.pdf>.
- James W. Jones, Laurence B. McCullough, Bruce W. Richman, "Limits of confidentiality: disclosure of HIV seropositivity," *Journal of Vascular Surgery*, vol. 38, no. 6 (2003): 1443-4.

- Is there a difference between confidentiality and privacy? *FindLaw.com* (2013).
<http://criminal.findlaw.com/criminal-rights/is-there-a-difference-between-confidentiality-and-privacy.html>http://www.medscape.com/viewarticle/506840_4.
- Waris Qidwal, Rumina Tabassum, Fahad Hanif Khan, et al., "Informed consent, privacy and confidentiality practised by doctors of a tertiary care hospital in a developing country," (2013).
<http://imsear.li.mahidol.ac.th/bitstream/123456789/153548/1/ijme2013v10n1p36.pdf>.
- Ayesha Humayun, Noor Fatima, Shahid Naqqash, et al., "Patients' perception and actual practice of informed consent, privacy and confidentiality in general medical outpatient departments of two tertiary care hospitals of Lahore," *BMC Medical Ethics*, vol.9, no. 1 (2008): 14.
<http://bmcmethics.biomedcentral.com/articles/10.1186/1472-6939-9-14>.

Clinical Ethics: 2.4: End of Life Issues

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Cases for Discussion

- **Case 1**

A COPD patient in his 70s does not want to be ventilated if he is hospitalized. He suffers from yet another bout of pneumonia and the need for ventilation arises. The doctors feel he could benefit from ventilation but his wishes are contrary to this and are documented and known. The family wants to do everything including ventilating.

Discuss the ethical dilemma the doctor faces.

- **Case 2**

A 25 year old with severe brain injury is being ventilated for 2 weeks. Prognosis was always poor and she slips into deep coma and finally is declared brain dead. Parents want to carry on with all treatment while physicians want to stop ventilation and other support.

Discuss ethical issues raised by this case.

- **Case 3**

A 45 year old has been on prolonged ventilator support for multi-organ failure and there is a possibility of his recovering and getting off ventilation. The patient is unconscious and his wishes are not known. However the family wants him extubated and wish to take him home since the prolonged treatment has drained all their resources.

What are the ethical issues here and what should the various considerations be for the physician?

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Teaching Video

- More than meets the eye. <http://vimeo.com/51505327>

End of life issues form a major part of ethics consults all over the world. This teaching video depicts one such situation where a neurosurgeon faces an ethical dilemma regarding the care of a quadriplegic patient with Downs Syndrome who is ventilator dependent but not brain dead. The process of engaging a distraught family member to ascertain the wishes of the family, and the deliberations of an ethics consultation are depicted in this film.

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Alan Meisel, “End-of-life care,” in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley, (2008): 51-54.
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End-of-Life Care

Alan Meisel

Highlights

Bioethics has long shaped policy concerning end-of-life decision-making, which involves numerous choices about what treatments to administer, taper off, cease, or withhold.

Traditionally, ethicists have considered patients’ wishes to be paramount.

Patients can express their wishes for end-of-life care in advance directives such as living wills, which are legally binding in all 50 states.

Some bioethicists now believe that other interests such as family members’ wishes should be considered in end-of-life decision-making.

Better brain imaging has shown important differences in disorders of consciousness that also challenge long-held ethical views on withholding treatment for persons with devastating brain injury.

Framing the Issue

End-of-life care and its many dilemmas capture public attention when they make national news. The story often involves a family seeking a court order to remove life support from a patient who, medical experts say, is in a vegetative state with no hope of recovery. The Schiavo case in 2005 was the most recent episode, but before that it was the Cruzan case in 1990 and the Quinlan case in 1976. When the news fades, so does public attention to end-of-life decisions. In reality, however, these decisions are omnipresent, and far more mundane than the headlines suggest. Approximately 2.5 million Americans die each year in the United States. For the nearly 70% of them who live out their final days in hospitals, nursing homes, and at home in hospice care, decisions must continually be made about what treatment to administer, what treatment to cease or withhold, what treatment to continue, and what treatment to taper off. While the fact of death remains inevitable, its timing is often very much a function of human agency. Once it was common to speak of nature taking its course, but today it is more common to view death as a matter about which people individuals at or near death, or their surrogates have some control. They may forestall death by choosing heroic measures to sustain life, such as resuscitation. Or they may hasten death by forgoing treatment, or by seeking to take action to bring life to an end. Because of its profundity, end-of-life decision-making occupies center stage in contemporary American bioethics. For three decades, medical professionals and policymakers have looked to bioethicists for advice in shaping medical guidelines and laws on end-of-life care.

Focus on Autonomy

Traditionally, the ethical and legal concerns with end-of-life care have focused on the interest of patients, an interest referred to as autonomy or self-determination. Autonomy is paramount for patients who possess decision-making capacity, but it is also a major consideration for patients who lack this capacity. Their wishes must be respected by the relatives or other health care proxies who make decisions on their behalf. According to traditional bioethical analysis, the centrality of the individual in contemporary

Western society requires that adults be permitted to make their own decisions about what medical treatment they want and do not want. To do otherwise would be an inexcusable invasion of individuals' interests in bodily integrity and in charting their own life plan in accordance with their own values, preferences, and interests. American law especially twentieth-century American law reflects and reinforces this ethical analysis. When individuals lose the capacity to make their own medical decisions, the interest in autonomy requires that decisions be based on the wishes that these people expressed earlier in their lives. This position has been adopted into law: all states recognize the legal authority of advance directives (living wills or health care powers of attorney). It is well accepted by bioethicists and the law that oral statements made by patients either instead of written advance directives or to supplement them may also be useful guides in determining what medical treatments they do and do not want. When individuals have not made manifest their decisions about medical care, the ethical and legal protocol is to implement a person's presumed wishes through a doctrine known as "substituted judgment." Under this doctrine, a surrogate must make decisions for a patient. If the patient has not appointed a surrogate in an advance directive, close family members are ethically and legally empowered to make decisions for the patient. Judicial deference to autonomy has been on the increase. It can be seen most clearly in cases involving Jehovah's Witnesses, who, for religious reasons, reject blood transfusions even when they are lifesaving. The trend in the 1960s and 1970s, when these cases first arose, was to override refusals of treatment. But since the 1980s the trend has been to honor them, even though doing so is predicted to cause the patient's death and may run counter to the interests of the patient, as well as the family, community, health professions, and society as a whole.

Challenging Autonomy

Some bioethicists now argue that autonomy has come to wield a kind of tyranny over end-of-life decision-making. They believe that overruling a patient's autonomy may be justified as follows.

Welfare of the Individual.

At times, the autonomous decisions of patients may seem to compromise their welfare. While an individual may be capable of making decisions, he or she may be incapable of reasoning about their personal impact. Under such circumstances, one might argue that the decisions are inauthentic they would not serve the person's best interest as that person would have defined it, had he or she been capable of reasoning. Traditional bioethical analysis contends that there is rarely, if ever, any justification for overruling the decisions of people with decision-making capacity. If a decision seems to be uncharacteristic of an individual inconsistent with the person's deeply held values, beliefs, and goals then inquiring about the soundness of the person's decision-making capacity is justifiable. But once that soundness is established, often by psychiatric testing, the fact that a decision seems to run counter to the individual's welfare is not an adequate ethical or legal basis for overturning it. If someone's decisions could simply be ignored when, in the view of others, they would be harmful to the individual's well-being, autonomy would become meaningless; people would have autonomy only when their decisions comported with some external standard, which is the antithesis of autonomy.

The Interests of Others

The centrality of autonomy is sometimes criticized for failing to regard the individual as part of a complex network of relationships. According to this view, the interests of the person's partner, children, parents, and others who are close must be taken into account in end-of-life decisions. Decisions that prolong life can entail prolonged suffering for patients and their close family members and friends. Decisions that shorten a patient's life also have consequences for others. Aside from the grief of the survivors, such decisions can impose burdens for example, the need to provide for a child who is still a minor. On the other hand, decisions to shorten a patient's life can also have possible benefits, such as the comfort of knowing that a loved one is no longer suffering, or an end to the stress and expense of care-giving.

Some bioethicists emphasize the importance of family and community interests in decision-making at the end of life. However, mainstream bioethical analysis rejects them as valid considerations unless the patient chooses to have them taken into account. So does the law. Although judicial decisions usually proclaim that an individual's right of self-determination must be balanced against the state's interest in the well-being of the individual's minor children, even that interest has virtually never been found to outweigh the patient's right of self-determination.

Interests of Health Caregivers

Relationships that dying individuals have with their medical and personal caregivers can become quite close and intense. The training, ethos, and codes of ethics of health care professionals buttress the feelings that arise from these relationships. Some people argue that permitting patients to make medical decisions that would shorten their lives could undermine the morale of health care professionals and thus their commitment to doing their utmost for every patient. Seen this way, one patient's decision could adversely affect the quality of care not just for that individual, but also for patients in general. The interests of caregivers have been invoked in a few legal cases involving patients' decisions to refuse medical treatment, but courts have not ruled that this interest outweighs a patient's right of self-determination.

Societal Interest in Allocation of Scarce Resources

Medical resources are scarce. That much is uncontroversial. But of all the reasons for overriding patients' autonomy, the societal interest in the efficient use of scarce health care resources is the most controversial. Some people believe that an individual's decision to continue medical care at the end of life must be weighed against the cost benefit ratio. In other words, overriding a patient's desire for a particular treatment is justified if the benefits of the treatment come at too high a price, or if there is compelling evidence that the treatment will provide no benefit.

Proponents further contend that it is ethically permissible indeed, ethically obligatory to deny resources if they will provide little or no benefit when the cost is being borne in whole or in large part by society: by taxpayers through Medicare, Medicaid, or other government programs, or through private insurance.

Opponents of this position acknowledge the scarcity of resources, but claim that such "bedside rationing" violates the physician's professional obligation to act solely in the patient's best interests, and that denial of treatment should be made at the policy, rather than the individual, level.

Another dilemma arises when a doctor thinks that a treatment is not beneficial, but a patient wants it anyway. Despite several dozen state supreme court opinions upholding patients' decisions to forgo life-sustaining medical treatment, there has been little discussion about what legal protection, if any, ought to be accorded a patient's wish to receive treatment that physicians do not consider worthwhile.

The law is clearer with regard to private health insurance companies and government payers for health care. Standard health insurance contracts, as well as Medicare and Medicaid policies, give these payers the right to refuse coverage for treatment deemed not medically necessary. Many patients have challenged these policies and prevailed, but the underlying principle that health insurance programs may deny payment for treatment of little or no benefit has never been seriously questioned.

Limits of Advance Directives

Only about 15–20% of Americans have written advance directives such as living wills, and their usefulness has long been questioned by the physicians who must draw guidance from them. Advance directives tend to be either too general or too specific to shed light on the issue to be decided. For now, the best directives seem to be those that designate a health care proxy, but even their effectiveness is open to question. Studies show that close family members do not always have a good reading of what a patient really wants. Despite the limitations, it is better to have an advance directive than not to have one.

Emerging Policy Issues

Although there is a consensus in law and clinical medicine about many of the ethically difficult issues in end-of-life decision-making, recent developments demand attention from public policymakers and legislators.

Palliative Care

The realization that patients' control over their dying needs to include adequate relief of pain has led to increased education of doctors about palliative care. It has also led to laws and medical policies that permit the use of palliative medications even if it unintentionally hastens death. In 2008, the American Medical Association adopted a policy supporting the use of sedation to the point of unconsciousness at the end of life in the rare circumstances when palliative measures are ineffective.

Physician-Aided Dying

The debate over the legalization of physician-aided dying may be heating up again with a referendum to legalize it on the Washington state ballot in 2008. It has been legally practiced in Oregon since 1997, with diminished public controversy and—all but the most stalwart opponents would agree a great deal of success (see chapter 30, “Physician-Assisted Death”).

Persistent Vegetative State

Advance directive legislation frequently cites persistent vegetative state as a reason for forgoing life-sustaining treatment. But recent developments in neuroscience have made it clear that this condition is not the unitary phenomenon it was once thought to be. Devastating brain injuries exist along a continuum. Some people who appeared to be permanently vegetative were then found, based on brain imaging, to have a surprising amount of brain activity, perhaps raising the hope that their condition may improve. This new insight into the brain raises the difficult question of whether life-sustaining medical treatment must be maintained for such persons in the absence of clear and convincing evidence in an advance directive that they would not want to be kept alive in such a condition (see chapter 4, “Brain Injury”).

Denial of Treatment

Perhaps the issue people least want to talk about may prove to be the most important because it is closely bound up with larger issues of health care reform. That issue is the denial of some forms of medical treatment at the end of life because of the belief that they provide little or no benefit and consume scarce health care resources in other words, rationing (see chapter 17, “Health Care Costs and Medical Technology”). Current practice by physicians, hospitals, and health insurers is sometimes to resist providing such treatment initially, but eventually to yield in the face of pressure from families. This practice is unlikely to change, unless there is a national consensus, embodied in legislation that limits the medical treatment that will be paid for by private and government health insurance to that which has been proven, if not cost effective, then at least effective.

Resources

Websites

1. www.abcd-caring.org – Americans for Better care of the dying. Includes news from the field, policy tools, and links.
2. www.caringinfo.org – caring connections. Resource page includes glossary of terms and brochures on several topics in end-of-life care.
3. www.growthhouse.org – Growth House, Inc. Includes RSS feed, fast facts, online reports, bookstore, and blogs on end-of-life care.
4. www.pbs.org/wnet/onourown/terms – companion Web site for the On Our Own Terms: Moyers on Dying series. Includes video from the series, resources, patient and community tools, and a glossary.
5. www.medicaring.org – the Palliative care Policy center. Includes free Pdf downloads of reports and monographs on end-of-life care and news from the field.

Recent News

1. Timothy Gower, "fatal flaw," Boston Globe, March 9, 2008.
2. Nicholas Bakalar, "Antibiotics Questioned in care at Life's end," New York Times, March 4, 2008.
3. Rob Stein, "devices can Interfere with Peaceful death; Implants Repeatedly Shock Hearts of Patients Who cannot Be Saved," Washington Post, December 17, 2007.
4. Jan Hoffman, "The Last Word on the Last Breath," New York Times, October 10, 2006.

Further Reading

1. Margaret P. Battin, "Terminal Sedation: Pulling the Sheet over our eyes," Hastings Center Report, September-October 2008.
2. Gerald S. Witherspoon, "What I Learned from Schiavo," Hastings Center Report, November-December 2007.
3. Joanne Lynn, Ekta Chaudry, Lin Noyes Simon, Anne M. Wilkinson, and Janice Lynch Schuster, Common Sense Guide to Improving Palliative Care, Oxford University Press, 2007.
4. Bruce Jennings, Gregory e. Kaebnick, and Thomas H. Murray, "Improving end of Life care: Why Has It Been So difficult?" Hastings Center Report Special Report, November-December 2005.
5. Joseph J. fins, "Rethinking disorders of consciousness," Hastings Center Report, March-April 2005.
6. Angela Fagerlin and Carl E. Schneider, "enough: The failure of the Living Will," Hastings Center Report, March-April 2004.
7. Joanne Lynn, Sick to Death and Not Going to Take It Anymore! Reforming Health Care for the Last Years of Life, University of California Press, 2004.

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Shahid Shamim, “To continue or discontinue treatment: What should families consider when deciding for an incompetent patient?” *Asian Bioethics Review*, vol. 5, no. 2 (2013): 159-61.

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To Continue or Discontinue Treatment: What Should Families Consider when Deciding for an Incompetent Patient?

Shahid Shamim

Letting go of someone you love is never an easy task, under any circumstances. Surrogate decision making for ending the life of a beloved one is perhaps the toughest of all. In the absence of a living will from incompetent patient, family members are considered the best option for this decision making, as they (presumably) know the patient’s preferences, and they would (presumably) cogitate the patient’s interest as the “only” consideration in the decision making process. Both the presumptions are arguable; however, they pose the two most important questions for the families to consider while deciding for an incompetent patient: 1) what would the patient have wanted under these circumstances?; and 2) which option is in the best interests of the patient? The two questions need to be approached in different ways: the first can only be answered by someone who knows the patient well enough to understand her values and preferences in life; the second requires complex scientific details regarding prognosis, options and associated sufferings for the patient (without any consideration for sufferings of others). Most families would keep both considerations while making the decision; however, information regarding one may take precedence over the other.

The given case seems to have multifactorial interrelated issues. What the patient would have wanted is not clear as she had given conflicting statements previously, which are likely to be desperate. The patient’s spouse, as the first choice for surrogate,¹ is weak and hesitant in decision making, plus there is an element of conflicting interests in his approach towards the patient’s care, considering the continuity of disability pension while the patient is alive. Would his wife also want the same for the benefit of her family?

A daughter, compared to sons, is generally considered to be emotionally closer to the mother. However, in this scenario the only daughter is unwilling to participate in the process of decision-making. (Does she know something about her mother’s wishes that she does not want to share with others?)

The eldest son, though not living with his parents, nevertheless, is willing to make the decision (probably filling in for his undecided father). The younger son is incompetent to undertake decisionmaking.

The complexity of family situation is not uncommon, especially in Eastern societies where individuals face difficulty in bearing the burden of decision making and decisions are reached by the whole family as a unit, guided by the “functional head” of the family.^{2,3} The situation gets worse if a family’s main decision maker becomes incompetent and the rest of the members unexpectedly find themselves in a plight to make decisions. Under such circumstances, the family can be encouraged to discuss their concerns, values, fears and their perceptions of what the patient would have wanted before collectively coming to an appropriate decision. The process can be facilitated by the attending physician.⁴ The process

of collective/shared decision making in resolving issues during end-of-life care has shown to be effective and satisfactory for the family as well as the physician.

The role of the attending physician is extremely significant in facilitating the process of decision-making, whether individually or shared.⁵ Moreover, in many societies (in Asia, Eastern Europe and Russia), physicians are culturally assigned an authoritative position of respect and reverence.⁶ Also, they may have more directly relevant information regarding a patient's wishes about end-of-life care than any family member, as evident in this case also. Patients and their families have high expectations from them to provide recommendations in addition to factual information to help families in decision making.^{3,7}

The question "What would the patient have wanted?" can be technically challenging in the context where patient has previously shown more than one aspiration. Especially in societies where benefits of the family as a unit supersede the individual's best interests, a patient may want an option which is not "the best" for her but harmonious for the unit. Decisions in such circumstances can be extremely difficult.

To resolve issues like the one at hand, the role of physicians and ethics committees become central in facilitating discussion within the family unit. The family members need reassurance and confidence regarding diagnosis, treatment options and their role in the process of decision-making. On the other hand, the family members themselves need to open up and put forth their queries, fears and insecurities. Families should consider what is best for the patient in her condition, given the available options of treatment.

References

1. Shepherd, L. (2005) Shattering the Neutral Surrogate Myth in End-of-Life Decision Making: Terri Schiavo and Her Family, Public Law and Legal Theory Working Paper No. 145, Cumberland Law Review, Social Science Research Network Electronic Paper Collection. Available at <http://ssrn.com/abstract=667441> [accessed 19 April 2013].
2. Searight, H.R. and J. Gafford (2005) Cultural Diversity at the End of Life: Issues and Guidelines for Family Physicians, *Am Fam Physician*, 71, 515–22.
3. Moazam, F. (2000) Families, Patients, and Physicians in Medical Decision making: A Pakistani Perspective, *The Hastings Center Report*, 30 (6), 28–37.
4. Bowman, K.W. and P.A. Singer (2013) Chinese Seniors' Perspectives on End-of-Life Decisions, *Social Science & Medicine*, 53 (4), 455–64.
5. White, D.B., C.H. Braddock, S. Beekneyei, and J.R. Curtis (2007) Toward Shared Decision Making at the End of Life in Intensive Care Units: Opportunities for Improvement, *Arch Intern Med*, 167, 461–7.
6. Johnston, S.C. and M.P. Pfeifer (1998) Patient and Physician Roles in End-of-Life Decision Making, *Journal of General Internal Medicine*, 13 (1), 43–5.
7. Andrews, M. (2011) Making End-of-Life Decisions is Hard on Family Members, *Kaiser Health News*. Available at <http://khn.org/news/michelle-andrews-on-end-of-life-care/>.

Useful Links

- Sameera Karnik, Amar Kanekar, "Ethical Issues Surrounding End-of-Life Care: A Narrative Review," In *Healthcare*, vol. 4, no. 2, *Multidisciplinary Digital Publishing Institute*, (2016): 24.
- Elizabeth J. Latimer, "Ethical care at the end of life," *Canadian Medical Association Journal*, vol. 158, no. 13 (1998): 1741-1747. <http://www.cmaj.ca/content/158/13/1741.full.pdf>.
- John S. Senn, "Writing" no-CPR" orders: must resuscitation always be offered?" *CMAJ: Canadian Medical Association Journal*, vol. 151, no.8 (1994): 1125. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1337229/pdf/cmaj00056-0031.pdf>.
- Dennis M. Sullivan, "End of Life Decisions 101," *Bioethics.com*. <http://www.bioethics.com/end-of-life-101>.
- "End of Life Care: An Ethical Overview," *Center for Bioethics University of Minnesota*, (2005). http://www.ahc.umn.edu/img/assets/26104/End_of_Life.pdf.
- Robyna Irshad Khan, "End of Life Care in Pakistan; Some Ethical Issues," *Journal of the College of Physicians and Surgeons Pakistan*, vol. 22, no. 12 (2012): 745-746. <http://www.jcpsp.pk/archive/2012/Dec2012/01.pdf>.
- Deborah L Kasman, "When is medical treatment futile?" *Journal of General Internal Medicine*, vol. 19, no. 10 (2004): 1053-6.

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Clinical Ethics

2.5: Euthanasia

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Euthanasia: Murder or Not: A Comparative Approach

Božidar Banović, Veljko Turanjanin

Abstract Background

Euthanasia is one of the most intriguing ethical, medical and law issues that marked whole XX century and beginning of the XXI century, sharply dividing scientific and unscientific public to its supporters and opponents. It also appears as one of the points where all three major religions (Catholic, Orthodox, and Islamic) have the same view. They are strongly against legalizing mercy killing, emphasizing the holiness of life as a primary criterion by which the countries should start in their considerations. Studying criminal justice systems in the world, the authors concluded that the issue of deprivation of life from compassion is solved on three ways. On the first place, we have countries where euthanasia is murder like any other murder from the criminal codes. Second, the most numerous are states where euthanasia is murder committed under privilege circumstances. On the third place, in the Western Europe we have countries where euthanasia is a legal medical procedure, under requirements prescribed by the law. In this paper, authors have made a brief comparison of the solutions that exist in some Islamic countries, where euthanasia is a murder, with Western countries, where it represents completely decriminalized medical procedure.

Keywords

Euthanasia, Murder, Legalization, Legal solutions

Introduction

Euthanasia, i.e. mercy killing is both historical and contemporary problem of medicine, law, ethics and religion, which is reflected in the multitude of interwoven concepts and different legislative solutions of that question all over the world. The debate over legalizing euthanasia is like earthquake,¹⁻⁴ sharply divides the scientific and unscientific public on its supporters and opponents, and although through literature pervades the opinion that this topic has been exhausted.⁵ In the maelstrom of issues that this topic opens, legislators all around the world try to find a practical solution, in order to resolve adequately the question of euthanasia. The line that separates admissible from impermissible merciful deprivation of life through the centuries has consistently been moved: in the direction of legalization of euthanasia and towards the complete ban of euthanasia. Globally, there are three main ways of regulation of mercy killing. One group of countries equates it with ordinary murder, while the second group represents the view that the euthanasia is privileged murder. Finally, in the third group euthanasia is decriminalized upon fulfillment of prescribed conditions. In Islamic countries, euthanasia is prohibited, both in the East⁶ and in the Bosnia and Herzegovina. It is seen as non-Islamic⁷ and it is equalized to the murder. Accordingly, in the countries where euthanasia is legally punishable, sentences vary from very lenient to the death penalty, as was the case in the Islamic countries.⁸

Since the debate over the legalization of active euthanasia does not subside for many years, its supporters and opponents have created strong organizations that represent their beliefs about the (im) morality and (in) feasibility of the same. The focus of the problem lies in the question what extent is necessary to

respect the life of terminally ill patients, and accordingly provide strong arguments. In other words, the question is whether in addition to the right on life, as a fundamental human right guaranteed by the European Convention of Human Rights and Liberties, there is a right to die, established through the right to self determination. Thus, opponents of legalization of active euthanasia, as primary argument, emphasize the holiness of life at all costs (which is supported primarily with arguments in Islamic and Christian religion, which prohibit any form of suicide),^{7, 9} while its supporters believe that the moral obligation of doctors is to end the life of terminally ill patient who is suffering, but they also highlight the strong individual autonomy in the matters of life and death. In short, both supporters and opponents summarize most of their arguments on the concept of respect for the patient, where they allocate four forms: a concern for the welfare for the patient, respect his wishes, respect for fundamental values of life and respects for the interests of the patient.¹⁰ Therefore, inter alia, any discussion of euthanasia leads to objections based on religious grounds. Secular arguments are rejected, because they “do not consider the crucial importance of having God as the creator of entire universe and human beings”.¹¹ This religious opposition to euthanasia is based on the claim that only someone who is not religious can consider euthanasia as one of the options in the life, but it cannot be for the people who have a religious orientation. In accordance with beliefs that prevail in some countries, their legislators resolve the issue of euthanasia in accordance with those beliefs, and some solutions will be discussed below. Among the reasons that explain the different treatment of euthanasia between countries, according to some authors, doctors often have a limited experience in this field, because they are not faced with such health condition of the patients.¹² This statement is correct. For example, physicians in Bosnia and Herzegovina do not have any experience with euthanasia.

In the world were crystallized three approaches in the legislative regulations of this matter, and we will briefly point out the solutions in some jurisdictions. Due to the volume of work, we will explain the legislations in which euthanasia is equated with murder, as well as legislations that represent quite the opposite solution.

First, in all Islamic countries, in accordance with religious beliefs, direct euthanasia is prohibited and is equated with the murder. Iran is no exception. In Iranian law, euthanasia is not explicitly mentioned in the legal texts, but there are some exceptions that lead to a more lenient punishment in some murder cases. However, the euthanasia is a murder with intent, and comes from a religious doctrine of Muslims. One study conducted among 55 physician shows that 98% of them think that euthanasia and physician-assisted suicide is a violation of human dignity, and they would not be willing to provide those.¹³ Because of the above, there are still no attempts for broader interventions for legalizing mercy killing.¹⁴ A recent survey in Turkey showed that 78% of patients and 63% of physician take a view that at least one form of euthanasia should exist (in this, it is pointed out that there are not significant differences between gender, marital status, education level and age of the patients with attitude about euthanasia).¹⁵

Such line of regulation of this sensitive matter kept the legislator in the Bosnia and Herzegovina, which has four similar criminal regulations, because this country has four legislations (Bosnia and Herzegovina, Federation of Bosnia and Herzegovina, Republic of Serbs, and Brcko District). First, in BiH, which is considered as a frontier between the Christian and Muslim Europe, live three ethnic groups (Muslim 40%, 32% Serbs and Croats 8%).¹⁶ These parts of the Bosnia do not have a same approach to the regulation of euthanasia, although at first glance it could be said that there is no difference in these criminal laws. It is a specific country, consisting of two entities (Federation Bosnia and Herzegovina, and Republic of Serbs), and the Brcko District. All three parts have their own legislation. For some considerations it is important to note that on this territory are valid three criminal codes: Criminal Code of Federation Bosnia and Herzegovina (further: CC FBH), Criminal Code of Brcko District (further: CC BD), and Criminal Code Republic of Serbs (further: CC RS).

In this part of the state applies a solution, which is defined as a crime deprivation of life another person's life, punishable by prison sentence of at least five years. The legislator makes a difference between this, ordinary murder, and the first degree murder which includes causing a death of another person in a cruel or insidious way; by reckless and violent behavior; on racial, national or religious reasons; for gain, to commit or conceal another serious crime; from ruthless revenge or other base motives; and the murder of official or military personnel in the performance of duties of security or the duty to maintain public order, arrest the perpetrator of the crime or guarding a person deprived of liberty (article 166. CC FBH). Almost identical provision is contained in the CC BD, which in the addition has a hate murder (article 163. CC BD). In addition to these two forms of murder, these laws recognize a provoked murder, manslaughter, murder of a child at birth, incitement to suicide and assisted suicide, and unlawful termination of pregnancy. Therefore, all those deprivations of life, which does not fall within in these specially defined, fall under ordinary murder. In this way, they observe euthanasia. In the part of country where live people of Islamic faith mercy killing is equated with the ordinary murder, while the legislator in the RS considers euthanasia as murder committed under mitigating circumstances. According to it, who deprive another person of life shall be punished with imprisonment at least five years (maximum is twenty-five years of imprisonment), but if the crime is committed under mitigating circumstances, the offender shall be punished with imprisonment from one to eight years (article 148. CC RS). It follows that the criminal laws of the FBH and BD are inspired by the group of legislations that do not privilege a mercy murder, believing that compassion for poor condition of the murdered is not a separate basis for a more lenient punishment. On the other hand, the legislator in RS is in the group that has a benevolent view on this issue.

Mercy killing in the Republic of Serbs from other forms of murder differs by motive of the execution, which by its nature is altruistic, because its goal is mitigating the pain and suffering of the victim/patient.^{17, 18} In the theory it is adopted an attitude that particularly mitigating circumstances occur circumstances in rare and specific situations. These circumstances legally and/or ethically fully justify particular murder or merely justify that the perpetrator could not otherwise act except to deprive a life of another human.¹⁹

However, it should be noted that the sharp equalization of these two types of murders is not desirable, because there are different reasons that lead to negative consequences.²⁰ View of euthanasia as a simple murder took the English legislator, where it resulted in the emergence of the death tourism, the phenomena where English inhabitants travel to Switzerland in the special hospitals and institutions to be euthanized.²¹ At the end of these considerations, we could mention that in the United States euthanasia is also prohibited and equalized with murder. However, four states (Oregon, Washington, Montana and Quebec) through court's precedents decriminalized physician assisted suicide, as a procedure that is very similar to the euthanasia.²²

Euthanasia in Netherlands

The first associations about the Netherlands for many years have been related to the beautiful canals, parks, windmills, rich museums, and unique architecture. Today, this country is particularly known for two things: decriminalization of enjoyment and distribution of light drugs and legalized euthanasia and assisted suicide.²¹ The first known case of euthanasia in the Netherlands dates back to the early fifties of the last century, when the physician performed euthanasia against his own brother, who was in terminal stage of the disease and that caused a lot of pain, so he repeatedly asked his brother to take his life.²³ However, this case had not attracted the attention of the public, unlike the case Postma in 1973, when the doctor was prosecuted because she injected a lethal dose of morphine to her mother, who had very poor health, but did not fatally diseased. In this highly emotional case, the court sentenced a doctor to one-year suspended sentence, but to whom execution is not occurred.^{23, 24} This was followed by cases Amsterdam in 1977, Rotterdam in 1981 and Alkmaar in 1982.

The rapid increase of number of performed euthanasia has led to questioning of its legalization, mainly thanks to the activities of the Dutch Voluntary Euthanasia Society (Nederlands Vereniging voor Vrijwillige Euthanasie (NVEE)). The Dutch parliament in the winter of 1993 reached a compromise between the two opposing concepts in the issue of euthanasia.²⁴ The parliament enacted the law that represents, generally speaking, a sort of codification of rules and procedures under which euthanasia is performed approximately three decades prior the enactment of the law. It is the most liberal law that regulates this matter in Europe. These standards and procedures are applied in medical practice and the practice of courts prosecuting crimes for deprivation of life from grace, and there is no extensive theoretical and legal doctrine on this issue, offering guidance in understanding the act of euthanasia.^{25, 26} Therefore, the law is only the “tip of the iceberg”.²⁷

The Netherlands prescribed the liberal conditions necessary for the execution of euthanasia. First, it should be noted that the Law on the termination of life does not contain the term euthanasia, but uses the term termination of life on demand, without giving its definition, although the guidelines in the “80 of the XX century used the term euthanasia.²⁸ According to the law, euthanasia is permitted upon meeting of the following requirements:

1. The request originates from the patient, and is given free and voluntary;
2. The patient suffers intolerable pain, which cannot be facilitated;
3. Patient is aware of his medical condition and perspectives;
4. Euthanasia is last sanctuary for patients, because there are no other alternative;
5. The doctor, who has to perform an euthanasia, consulted a colleague who has experience in this field, and which has examined a patient and agreed that all conditions are met for euthanasia or assisted suicide, and
6. Euthanasia or assisted suicide is performed with the necessary care.²⁵

Therefore, the physician who performs euthanasia will be protected from prosecution only if he meets all substantive and procedural requirements.²⁹ That is why euthanasia is subject of control. In order to get the information whether they committed a crime, doctors sometimes have to wait a period of eight months from performed euthanasia.³⁰ In fact, after the euthanasia doctor has an obligation to fill out the appropriate protocol and inform about euthanasia the municipal pathologist, by filling out the appropriate form and attaching all necessary documents.³¹

Although at one point in this country a question of the existence of culture of death was raised, which was caused by number of early deaths of patients, the Royal Dutch Medical Association (Koninklijke Nederlandsche tot beverdering der Geneeskunst (KNMG)), recently, inter alia, reiterated that the law on termination of life must be an exception, not the rule, and that this procedure will never become a standard,³² although a number of doctors do not consider euthanasia as a exceptional measure, which would require the exercise of social control of it.³³ However, the studies show that in the Netherlands euthanasia is more accepted way of completion of life. Compared to 1975, when 52, 6% of the population supported this form of deprivation of life; in 1988 this percentage was 88%. The fact that is especially interesting, if we consider that, the Catholic Church is strongly against euthanasia, is that the 74% of the Roman Catholic religion support euthanasia.²⁹ Proponents of this form of deprivation of life find that the key determinant in this process should be self-determination, because respect of life includes the avoidance of undignified death.³⁴ In addition, legal and medical theory state that patients are not afraid of euthanasia, but their biggest fear is that their request for euthanasia will be denied.³⁵

With regard to the statistics of euthanasia, we can note that there are significant differences in relation to the different years of observation. Thus, in 2001, in the Netherlands were 3,500 cases of euthanasia, while in the 2005 there were 2,297 of performed euthanasia, which represent 1, 7% of all deaths in the country.³³ However, in the 2010 there were 2, 910 recorded cases of euthanasia, 182 cases of assisted

suicide and 44 cases with elements of both kinds of these deprivation of life, representing 2, 3% of total deaths.³⁶ In the following year, there were 3,695 notifications, which represent a significant increase in the number of deaths in this way, compared with the previous year.³⁷ The main reason in all observed periods that led the patients on this step was existence of cancer. However, it is important to mention the fact that in each of the analyzed years there are several cases where the doctor did not comply with the rules of procedure. For example, in 2011 are recorded four such cases.³⁷ In contrast to this fact, the prosecutions are rare. For instance, between 1981 and 1997 there were prosecuted only 20 doctors, of whom nine were convicted, but on the symbolic sentence (six to the suspended sentence and three on fines).²³ Then, based on the above, we should point out that in the Dutch professional public there are perceptions that the cases of euthanasia in fact do not exist. Reason for this opinion is that most of the cases are related with patients who are terminally ill (cancer), who have greatly suffered and received massive doses of medicaments.³⁵

Euthanasia in Belgium

The idea of legalizing euthanasia in Belgium emerged at the beginning of the 80s of the XX century, in the action of two associations for the right to die with dignity. However, unlike Netherlands, Belgium did not have a long history of performing euthanasia and prosecuting doctors, and it could not establish appropriate guidelines and led the legislator to the faster reaction. In the same time, that does not mean that there were doctors who practiced in the shadows and supported the idea of euthanasia.³⁴ According to some studies, those were conducted in the late 90s of the last century, approximately 5% in Flanders of the total numbers of deaths accounted for euthanasia, i.e. on the use of drugs for the purpose of shortening of patient's life. Special attention was aroused by a fact that the 3, 2% to 3, 8% of the deprivation of life was without explicit request of the patient.³⁸

Euthanasia law was enacted on 16 May 2002. In Belgium, before the enactment of the law, there were no guidelines or case law regarding to mercy killing. Therefore, Belgian law is much more detailed than Dutch law, which was more a result of some sort of codification of regulations.²⁷ For these reasons, the Belgian legislator issued detailed provisions, in order to provide a greater level of protection and security to doctors and patients.³⁹

Characteristic of this law is that legislator in the title as well as in the text, uses a term euthanasia, which is defined as intentionally taking the life of another person upon his request. The definition, as a term, from one side, is taken from the Dutch law and theory; while on the other hand, the current Dutch law does use neither the term nor the definition. At this point, it is necessary to draw attention to the fact that the Belgian euthanasia law does not specifically regulate assisted suicide, and the reason for that can be found in the fact that it has never been a social need to regulate assisted suicide as a separate crime, and the difference between it and mercy killing is minimal. Therefore, regulation of assisted suicide in this law was superfluous – such as excessive mention that physicians has to take this procedure with due care and attention.⁴⁰

The requirements upon which the act of euthanasia will not constitute a criminal offence are set in almost the same way as in the Dutch legislation. Before conducting the deprivation of patient's life, a physician has to inform the patient about his health and life expectations, to discuss with him about the request for euthanasia and about the options for palliative care, as well as the consequences of the decision. The patient and doctor have to work together and conclude that there is no reasonable alternative for the patient's situation, and that his request was made voluntary. Then, the doctor must be convinced in the patient's permanent physical and/or mental suffering, and to the fact that the request was made permanent.

To be sure, the physician needs to do more interviews with the patient, but spread over a longer period, in order to follow better the development of state of his mind. The physician also has to consult another

doctor about the condition of the patient, and to inform him of the request for euthanasia. Another doctor will review medical records and talk with the patient. He has to be sure in patient's suffering that cannot be mitigated. His findings should be documented. He has to be completely independent from the patient and the acting physician as well, and must be competent to give an opinion on the disease in question, which will inform a patient. The next requirement is related with medical staff, first, with nurses. Namely, if the concern about patient was engaged those who had a constant contact with the patient, the doctor needs to talk with them about the request for mercy killing.^{40, 41}

The number of performed euthanasia in Belgium slightly increased after legalization, and raised the question of whether the deprivation of life of grace is normal medical practice or not. According to the Report from 2004, in 2003 259 merciful deprivation of life from mercy was conducted, which is average about 17 euthanasia per month, i.e., 0, 2% of total number of deaths in this country. The largest number of patients as a reason for that act noted various incurable kinds of cancer, and about 60% of them asked to perform euthanasia in hospital. In 2004 and 2005 there were performed 742 legal euthanasia (that was 0, 36% of total number of deaths).⁴² Of these, 77% of the patients were aged between 40 and 79 years old, and from the total number of euthanasia deaths, 83% of patients suffered from cancer.⁴³ However, the number of performed euthanasia has grown rapidly over the coming years, so in 2008 about 500 euthanasia was reported (which is slightly less than the previous year, when they reported 924 deaths), and in 2009 there were 1.526 euthanasia deaths, which is 0, 7% of total number of deaths. In approximately 80% of cases, the reason for requiring mercy killing was a cancer.⁴⁰ According to the Report from 2012 (which refers to the period 2010-2011 year), the reason for euthanasia was cancer in 75% cases.⁴⁴

Euthanasia in Luxembourg

Luxembourg is the third country in Europe which legalized euthanasia, and which legislator brought euthanasia and assisted suicide law on 20 February 2008, and which entered into a force on 16 May 2009 year.⁴⁵ Compared to the last two described laws, this law is similar, but not identical with them. The conditions for this procedure are set more or less on the same way. As far as the kinds of suffering that patient have to endure, Luxembourg's legislator adopted the solution from the Belgian law, and allows mercy killing in the case of psychological pain. An important difference with the previously described legislations lies in the fact that physician has to seek prior approval from the National Council in order to perform a euthanasia.³¹

Conclusion

Deprivation of life from compassion throughout the history of humanity appears as a question that engrosses the attention of lawyers, doctors, sociologists around the worlds. In certain stages of development of civilization it represented a permitted form of depriving another person's life, while in the other stages was strictly prohibited. Today's legislators basically occupying three positions, so, they prohibit euthanasia and equate it with ordinary or privilege murder, or allow it under the assumption of meeting of prescribed requirements. Bypassing the countries that privilege euthanasia as less serious murder, in this paper we have dealt with some legislations that this phenomenon strictly prohibit, and those that deprivation of life out of compassion treat as a permitted medical procedure. In Islamic countries, such as Iran, Turkey and part of Bosnia and Herzegovina, euthanasia is an ordinary murder, punishable by serious criminal sanctions. At the opposite pole are the Western European countries, more specifically, the Benelux countries (Netherlands, Belgium and Luxembourg), in which deprivation of life from the grace does not constitute a crime, if it was carried out in accordance with the clearly defined legal rules and medical procedure. In this way, we show how a life situation may be in different legal areas regulated in completely different way. Exactly this lack of harmony in the legislative solution in some European and American countries has led to the some adverse events, such as death tourism, as a phenomenon where inhabitants of one country, where euthanasia is prohibited, travel to another state where it is allowed, and where physicians can perform euthanasia. In order to avoid this, it is necessary to

achieve a certain degree of harmonization of legislations, or to set appropriate limit in the legislations that legalized euthanasia. However, how it is possible to achieve, time will show.

Ethical Considerations

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.

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References

1. McCall S (1999). Euthanasia: The strengths of the middle ground. *Med Law Rev*, 7 (2): 194-207.
2. Pereira J (2012). Legalizing euthanasia or assisted suicide: the illusion of safeguards and controls. *Current Oncology*, 18 (2): 38-45.
3. Downie J, Chambaere K, Bernheim JL (2012). Pereira`s attack on legalizing euthanasia or assisted suicide: smoke and mirrors. *Current Oncology*, 19 (3): 133-138.
4. Pereira J (2012). Casting stones and casting aspersions: let`s not lose sight of the main issues in the euthanasia debate. *Current Oncology*, 19 (3): 139- 142.
5. Williams G (1969). Euthanasia legislation: A rejoinder to the non-religious objections. In: *Euthanasia and the Right to Death: the Case for Voluntary Euthanasia*. Ed. A. Downing, London, pp. 134-147.
6. Sajid A (2003). Death and Bereavement in Islam. Available from: <https://www.yumpu.com/en/document/view/11550914/death-and-bereavement-in-islam-muslim-council-of-britain>.
7. Aramesh K, Shadi H (2007). Euthanasia: An Islamic Ethical Perspective. *Iran J Allergy Asthma Immunol*, 6 (5): 35-38.
8. Ebrahim AM (2007). Euthanasia (Qatl al-rahma). *JIMA*, 39: 173-178.
9. Haseeb Ansari A, Sambo AO, Abdulkadir AB (2012). The Right to Die Via Euthanasia: An Expository Study of the Shari'ah and Laws in Selected Jurisdictions. *Advances in Natural and Applied Sciences*, 6(5): 673-681.
10. Harris J (1995). Euthanasia and the value of life. In: *Euthanasia Examined – ethical, clinical and legal perspectives*. Ed. Keown J, Cambridge, pp. 6-22.
11. Klajn-Tatić V (2005). Religious views on active euthanasia. *Strani pravni život*, 3: 171-177. (Serbian).
12. Berghmans T, Lossignol D (2012). Euthanasia: from ethical debate to clinical reality. *Eur Respir J*, 40 (4): 804–805.
13. Karami K, Maria C, Nasibeh K (2012). Physicians` attitude about euthanasia and assisted suicide. *Int J Med Med Sci*, 4 (6): 138-141.
14. Noori F (2014). Euthanasia in Iranian Criminal System. *Research Journal of Applied Sciences, Engineering and Technology*, 7 (11): 2182-2184.
15. Taghadosi nejad F, Okazi A, Maghareh zade Esfehiani M, Yousefi Nejad V (2014). Comparison of Attitude of Physicians and Patients about Euthanasia in Tehran`s University of Medical Sciences Hospitals in 2012-2013. *SJFM*. 20 (4 and 1): 377-384.
16. Frucht R (2000), *Encyclopedia of Eastern Europe: From the Congress of Vienna to the fall of Communism*. New York & London: Garland Publishing.
17. Babić M, Marković I (1997). *Krivičnopravna zaštita ljudskog života*. Banja Luka: Faculty of Law, University of Banja Luka, Bosnia and Herzegovina. (Bosnian).
18. Jotanović R (2010). Right to life and/or right to death in the context of euthanasia. *Pravna riječ*, 7 (24): 179-192. (Serbian).
19. Babić M (1997). Right to life and privileged murders. *Pravni Život*, 46 (9): 83-98. (Serbian).
20. Turanjanin V (2012). Moral inadmissibility differentiation of active and passive euthanasia. *Pravni Život*, 61 (9): 509-522. (Serbian).
21. Turanjanin V (2013). The origins and possibilities of development of death tourism in Western Europe. In: *Service Law*. Ed. M Mićović. Faculty of Law, University of Kragujevac, Serbia, pp. 787-803. (Serbian).
22. Turanjanin V (2012). Positive legal regulation of some specific medical service in the United States – physician assisted suicide. In: *XXI century –Century of Services and Service Law*. Ed. M Mićović. Faculty of Law, University of Kragujevac, Serbia, pp. 349-362. (Serbian).

23. Cohen-Almagor R (2001). Euthanasia in the Netherlands: the Legal Framework. *MSU-DCL J Int Law*, 10: 319-342.
24. Belian J (1996). Deference to Doctors in Dutch Euthanasia Law. *Emory International Law Review*, 10: 255-296.
25. Keown J (2004). *Euthanasia, Ethics and Public Policy*. Cambridge: Cambridge University Press.
26. Dunsmuir M, Smith M, Alter S (1998). Euthanasia and assisted suicide. Available from: <http://publications.gc.ca/CollectionR/LoPBdP/CIR/919-e.htm>.
27. Nys H (2002). Euthanasia in the Low Countries – A comparative analysis of the law regarding euthanasia in Belgium and Netherlands. *Ethical Perspectives*, 9 (2-3): 73-85.
28. Groenhuijsen M (2007). Euthanasia and the Criminal Justice System. *Electronic Journal of Comparative Law*, 11.3: 1-25.
29. Leenen HJJ (2001). The Development of Euthanasia in the Netherlands. *Eur J Health Law*, 8 (2): 125-134.
30. Sheldon T (2011). Dutch doctors complain about long wait for judgments in cases of euthanasia. *BMJ*. Available from: <http://www.bmj.com/content/343/bmj.d5768>.
31. Turanjanin V (2012). Mercy killing and assisted suicide – insight on the solutions in law in countries which decriminalized them. *Herald of Law*, 3 (2): 15-36. (Serbian).
32. Shariff MJ (2012). Assisted death and the slippery slope – finding clarity amid advocacy, convergence, and complexity. *Current Oncology*, 19 (3): 143-154.
33. Cohen-Almagor R (2009). Critical Remarks on the Dutch Policy and Practice of Euthanasia and Proposed Guidelines for Physician-Assisted Suicide. In: *From New Medical Ethics to Integrative Bioethics*. Ed. A. Čović, N. Gosić, L. Tomačević, Zagreb, pp. 197-216.
34. Shariff M (2011). A Perfection of Means, and Confusion of Aims: Finding the Essence of Autonomy in Assisted Death Laws. *Health Law Can*, 31 (4): 81-148.
35. Cohen-Almagor R (2003). Non-Voluntary and Involuntary Euthanasia in Netherlands: Dutch Perspectives. *Issues in Law and Medicine*, 18 (3): 239- 257.
36. Regional euthanasia review committees, Annual report (2010). Available from: http://www.euthanasiecommissie.nl/Images/JV%20RTE%202010%20ENGELS%20%28EU12.01%29_tcm52-30364.pdf.
37. Regional euthanasia review committees, Annual report (2011). Available from: http://www.euthanasiecommissie.nl/Images/R TE.JV2011.ENGELS.DEF_tcm52-33587.PDF.
38. Cohen-Almagor R (2009). Belgian euthanasia law: a critical analysis. *J Med Ethics*, 35 (7): 436-439.
39. Srinivas R (2009). Exploring the Potential for American Death Tourism. *MSU Journal of Medicine and Law*, 13 (1): 91-122.
40. Turanjanin V (2013). Death with dignity in Belgium. In: *XXI century – Century of Services and Service Law*. Ed. M Mićović. Faculty of Law, University of Kragujevac, Serbia, pp. 223-237. (Serbian).
41. The Belgian law of May 28, 2002.
42. White H (2012). Over 30% of Euthanasia Cases in Belgian Region Did Not Give Consent: Study. Available from: <http://www.lifesitenews.com/news/over-30-of-euthanasia-cases-in-belgian-region-did-not-give-consent-study>.
43. Cohen-Almagor R (2009). Euthanasia Policy and Practice in Belgium: Critical Observations and Suggestions for Improvement. *Issues in Law & Medicine*, 24 (3): 187-220.
44. Commission fédérale de contrôle et d'évaluation de l'euthanasie (2012). Cinquième rapport aux chambres législatives. Available from: http://www.health.belgium.be/filestore/19078961_FR/Rapport%202012%20fr.pdf.
45. Legislation reglementant les soins palliatifs ainsi que l'euthanasie et l'assistance au suicide, *Memorial Journal Officiel de Grand-Duché de Luxembourg*, Recueil de legislation, 16 mars 2009.

Useful Links

- Gail Van Norman, "The Ethics of Ending Life: Euthanasia and Assisted Suicide," Part 1. *CSA Bulletin*, (2012): 78-82.
https://csahq.org/docs/default-source/news-and-events-docs/csa-bulletin-docs/volume-61-number-1/end_of_life_61_1.pdf?sfvrsn=2.
- Ezekiel J. Emanuel, Bregje D. Onwuteaka-Philipsen, John W. Urwin, et al., "Attitudes and practices of euthanasia and physician-assisted suicide in the United States, Canada, and Europe," *The Journal of the American Medical Association*, vol. 316, no. 1 (2016):79-90.
- Božidar Banović, Veljko Turanjanin, "Euthanasia: murder or not: a comparative approach," *Iranian Journal of Public Health*, vol. 43, no. 10 (2014): 1316.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4441884/pdf/IJPH-43-1316.pdf>.
- Jeffrey P. Bishop, "Euthanasia, efficiency, and the historical distinction between killing a patient and allowing a patient to die," *Journal of Medical Ethics*, vol. 32, no.4 (2006): 220-224.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2565787/pdf/220.pdf>.
- Paula McCormack, "Quality of life and the right to die: an ethical dilemma," *Journal of Advanced Nursing*, vol. 28, no. 1 (1998): 63-69.
<http://www.hadassah.org.il/media/2004764/quality%20of%20life.pdf>.
- "Euthanasia and assisted suicide" Arguments, *NHS Choices*.
<http://www.nhs.uk/Conditions/Euthanasiaandassistedsuicide/Pages/Arguments.aspx>.
- Wafa Hassan, Farah Ahmad, Aisha Malik, et al., "Knowledge and attitude regarding euthanasia among medical students in the public and private medical schools of Karachi," *The Journal of the Pakistan Medical Association*, vol. 63, no. 2 (2013): 295-299.
http://www.jpma.org.pk/full_article_text.php?article_id=402.1.
- Muhammad Nasir Afzal, Rabia Latif, Tahir Ahmad Munir, "Attitude of Pakistani doctors towards euthanasia and assisted suicide," *Pak Armed Forces Medical Journal*, vol. 60, no. 1 (2010): 9-12.
<http://www.pafmj.org/showdetails.php?id=304&t=o>.
- Haider Rifaat, "Understanding euthanasia and its moral implications in Pakistan," *The News Tribe* (July 27, 2016). <https://www.thenewstribes.com/2016/07/27/understanding-euthanasia-moral-implications-pakistan-haider-rifaat/>.

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www.dawn.com/news/1122765.

Open source document.

Australian Couple Leave Adopted but Disabled Baby with Thai Surrogate

BANGKOK: Well-wishers on Friday had raised nearly \$100,000 for a baby reportedly left with his surrogate Thai mother after his Australian ‘parents’ discovered he had Down’s Syndrome and returned home with his healthy twin sister.

Pattaramon Chanbua from Chonburi province, southeast of Bangkok, agreed via an agent to be a surrogate for the couple for a fee of \$14,900, giving birth to twins a boy and a girl in December, according to press reports.

But when the Australians discovered the boy, named Gammy by his surrogate family, had Down’s Syndrome they abandoned him in Thailand and returned to Australia with only the healthy girl, Australia’s ABC said.

“The money that was offered was a lot for me. In my mind, with that money, one, we can educate my children, two, we can repay our debt,” said Pattaramon, already a mother to two children, in an interview with the broadcaster in Chonburi.

But instead the 21-year-old was left to care for the boy who also suffers from a life-threatening heart condition requiring expensive treatment she cannot afford, according to ABC.

“I don’t know what to do. I chose to have him. I love him, he was in my tummy for nine months,” she said in the interview.

Pattaramon has never met Gammy’s Australian ‘parents’, according to Thai newspaper Thairath, which broke the story about Gammy last week, and their identities remain unknown.

“They (the surrogacy agency) told me to carry a baby for a family that does not have children. They said it would be a baby in a tube,” she said.

A spokesman for Australia’s foreign affairs department said Canberra was “concerned” by the reports and was in consultation with Thai authorities over surrogacy issues.

“The alleged circumstances of the case raise broader legal and other issues relating to surrogacy in Thailand,” he said.

Many foreign couples travel to Thailand, a popular medical tourism hub, to use its in-vitro fertilisation (IVF) services despite the unclear legal situation surrounding surrogacy.

Tares Krassanairawiwong, a Thai public health ministry official, said it was illegal to pay for surrogacy in Thailand.

“Surrogacy can be done in Thailand but it has to comply with the laws. A surrogate has to be related to the intended parents and no money can be involved.”

The reports about Gammy’s abandonment have triggered hundreds to donate to a fundraising page created for him last week.

By late Friday the “Hope for Gammy” page had raised more than \$98,000. It also carried scores of comments, many of which expressed outrage at the boy’s abandonment by his ‘parents’.

“May this selfish and heartless couple be exposed and shamed for this horrible neglect,” said one.

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Sharmeen Khan, "Surrogacy in Pakistan: Legal perspectives," *Bioethics Links*, vol. 10, no. 1 (2014).
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Surrogacy in Pakistan: Legal Perspectives

Sharmeen Khan

In 2005, a married couple of Pakistani origin living abroad decided to enter into a surrogacy arrangement with a Pakistani woman. The husband, Farooq, came to Pakistan, presumably entered into a nikah (marriage) with a lady called Farzana, and through an IVF process started a chain of events which would lead to the first court decided case of surrogacy in Pakistan.

As soon as the baby was born, Farzana left the child with Farooq. However, a few days later, she decided to recover the child and filed a case against Farooq under the Code of Criminal Procedure (CrPC) section 491 (recovery of detainee) and the court awarded her custody. Farooq then moved the local Bench of the High Court where he stated that he had a contract of surrogacy; he also relied on the Guardian and Wards Act, 1890 and petitioned the court to be awarded guardianship under section 25. In raising this petition, he stated that he was wealthier than Farzana, being a practicing doctor. However, the court was not satisfied that wealth alone could be a ground of custody and since Farooq had not admitted to a marriage with Farzana, it decided that there was no link between Farooq and the child. Therefore, on merits, the court allowed the child to stay in the custody of Farzana and also noted that surrogacy had no legal status in Pakistan.

Farooq appealed against this decision but in its Appeal Judgment (in November 2012), the High Court of Lahore upheld the two previous orders. In its reasoning the court stated that children belonged to the bed or conjugal relationship, and their custody rested with parents who admitted to having a marital contract with each other. Since Farooq denied that he was wedded to Farzana, he could not claim any rights over the child. However, as Farzana was undeniably the mother, she was the child's rightful guardian. Further, the Court once again underlined the null and void status of a surrogacy contract as the law of the land did not recognize surrogacy. This ended a seven year legal battle on the custody of the child (P L D 2013 Lahore 254).

What this case has served to illustrate is that a contract, whereby a woman (whether as a biological donor or as purely a gestational parent) carries a child for another couple, would neither be recognized as legal nor be enforceable in Pakistan. In fact, Pakistan like many other countries does not have a legislative framework that regulates surrogacy. Consequently, a surrogacy arrangement would be ignored and the court would rely on the Guardian and Wards Act, 1890 to award custody to a fit parent.

The question that then arises is whether there is a possibility of creating a framework of laws related to surrogacy in Pakistan. In order to fully answer that question (in line with the constitutional principles requiring that no law may contravene the Quran and Sunnah) we would have to determine the position held on surrogacy by the majority of Islamic jurists which is beyond the scope of this paper. However, what we can try and understand are the challenges that lawmakers may face should they try to develop such a framework.

The first challenge would be to determine who would be deemed the mother in a Court of Law. The question of fatherhood is not at stake as issues of surrogacy tend to revolve around the rights of the gestational/birth mother versus that of the couple in the arrangement. In the Quran it is stated in Surah al-Mujadalah (58:2) “their mothers are only those who conceived them and gave birth to them.” This clarifies that the mother will be deemed the woman who has given birth. Therefore, in cases where there are no questions of DNA, the surrogate mother would be the mother who physically carried and gave birth to the baby. However, in the case where the birth mother is separate from the donor egg mother and we do involve considerations of DNA, the above (ayat) (verse) does not provide a clear answer. It clearly stipulates that a mother is one that has both (a) conceived and (b) given birth. It does not address the situation of the conceived mother being separate from the mother who gave birth. If the two are separate then either of them may be deemed a mother, a situation that may open a Pandora's Box of complexities: If either of them can be a mother, then can neither of them claim the right to motherhood?

The second challenge is that of the provisions of the Ordinance impacting the legitimacy of the arrangement. Surrogacy essentially involves questions that relate to the legitimacy of procreation outside a marriage contract. In absence of a marriage contract between a donor father and surrogate mother, the provision of Pakistan Penal Code dealing with (adultery) may also come in to play. In the case of Farooq vs Farzana, the honorable Judge stated that the child belongs to the bed and absent a lawful marriage, a question of adultery could have been brought into this equation. Given the legal history of Pakistan, it would be challenging to establish the absence of coitus if someone outside the arrangement did in fact make an accusation. On the other hand, if a marriage contract does exist then the very concept of a surrogacy contract becomes irrelevant. The laws on marriage, its dissolution and the guardianship laws adequately provide for the custody of minors coming from a marriage.

The third, and I believe, the most significant challenge, is one that deals with the legitimacy of a surrogacy contract itself that is, a contract which would allow a woman to rent out her uterus. If a legislative framework is created that regulates a surrogacy relationship, can it be enforceable, and under what terms?

Surrogacy contracts, in countries where they are recognized, are often divided between commercial and altruistic. In Pakistan, the idea of a surrogacy contract on a commercial basis may be considered illegal because it would mean that the subject of the contract is a uterus. It may open up questions about the right of a person to rent out parts of their body and it may lead to exploitation, specifically in a country like Pakistan where there is a large economic divide and a history of bonded labor. Further, it would require a deeper analysis of an individual's right to rent out a body. Is it like providing manual labor? Or could it be equated to a form of prostitution?

Altruistic surrogacy, however, has a different basis from commercial surrogacy and one may imagine a situation where it may be considered legal in Pakistan. However, Pakistani courts do not always have the ability to gauge the true intentions of parties and it would be difficult to establish that a surrogacy contract was indeed altruistic unless a relative has been a surrogate parent. We may draw an analogy to the Human Organ and Transplant Donation Ordinance of 2007 which prohibited all forms of commercial donation and only allows filial proximity for live donors.

Even in UK, where surrogacy is regulated, a surrogacy contract is unenforceable. This means that it is legal but should the surrogate mother decide to violate the contract, the other party would not be able to enforce it. In Pakistan, taking all the discussed factors into account, it seems that we will not be developing surrogacy laws anytime soon and any arrangement of this nature would have to be essentially a private one which would be legally unenforceable and would depend on the trust all parties have on each other. Further, it would need the added protection of legalizing instruments, such as a lawful marriage, which could create its own complications.

References

- Surrogacy. <http://en.wikipedia.org/wiki/Surrogacy>. Accessed 2014
- The Islamic Ruling on Surrogate motherhood. <http://www.ilmgate.org/the-islamic-ruling-on-surrogate-motherhood/> Accessed 2014

(References for this article are available in the online version of *Bioethics Links*, vol. 10, no. 1)

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Malini Karkal, "Surrogacy from a feminist perspective," *Indian Journal of Medical Ethics*, vol. 5, no. 4 (1997): 115-116.
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Surrogacy from a Feminist Perspective

Malini Karkal

Introduction

As commonly understood, a surrogate mother is one who is hired to bear a child that she turns over at birth to her employer. The word 'surrogate' means 'substitute'. Nelson and Nelson¹ point out that 'mother' is the person who gives birth to a child.

It would seem, then, that the surrogate mother would be someone who has no genetic contribution to make. The embryo is surrendered to her and she then takes the place of the mother. The person who does the surrendering is the real mother, not a surrogate in any form.

They further point out that our current practice with the label indicates that in cases where social and biological mothering come apart, the social sense of mothering is regarded as significant?, and overrides biological mothering. It is also important to note that our patriarchal society gives the baby the man's family name. Male babies also inherit their father's property.

In spite of the fact that the mother makes a much larger contribution to the birth of the baby, the baby is considered illegitimate if the mother is not the legal wife of the man. Surrogacy denies even the recognition of the woman's biological contribution.

Surrogacy has existed from Biblical times. Altruism prompted a woman to try to help another who for biological reasons was not capable of bearing her own child.

Surrogacy has become controversial from the time it involved money and has now become a big business. It involves lawyers and psychologists, contracts and highly paid go-betweens and anonymous payers. For this reason surrogacy is often called 'baby selling' and surrogates 'whores'. It is seen as a way of exploiting women for the benefit of men who ensure that the baby has their genes.

Trials of the Surrogate Mother

In child bearing, the man's role is limited to his contribution of the sperm. The patriarchal society is built on man's protection of his position in the family so that he can be assured that his name will be continued and property will pass to his heirs.

In surrogacy, one man purchases the rights of another. Some men react to this 'encroachment' on their rights. Women who participate in surrogacy programmes report that their partners, initially agreeable to their undertaking the responsibility, often change their attitude after they take on their new role. One American woman told of how her fiancée left her for another woman. The husband of another surrogate mother would not look at her after she was inseminated. "He calls me a whore, prostitute and rent-a-womb. My husband felt it threatened his manliness."²

Children, too, become victims. Some are teased and tormented by friends. Others have shown shame at what their mothers did. Surrogates have to carefully consider how they will explain the pregnancy to their existing children, especially if they are young, and ensure that there is no resentment.

Commerce

Surrogacy turns a normal biological function of a woman's body into a commercial contract. Surrogate services are advertised. Surrogates are recruited and operating agencies make large profits. The commercialism of surrogacy raises fears of black market and baby selling, breeding farms, turning impoverished women into baby producers and the possibility of selective breeding at a price. Surrogacy degrades a pregnancy to a service and a baby to a product. Experience shows that like any other commercial dealing the 'customer' lays down his/her conditions before purchasing the goods.

'Some agencies insist that the surrogate must be married and be a mother of at least one healthy child, be medically and psychologically fit, abstain from cigarettes, alcohol and any other drugs during pregnancy and must agree to give up her parental rights after the baby is born. Her husband must also pass tests. The couple must present a medical report on their health, the results of semen analysis showing the husband is fertile, a laboratory report on their blood type and their marriage certificate. The agency arranges the contract, life insurance for the surrogate's family (should she die during pregnancy or childbirth) and life insurance or a will for the child should the (contracting) couple die before the child is born.²

The surrogate may be forced to terminate the pregnancy if so desired by the contracting couple and she will not be able to terminate it if it is against the desire of the couple. She has difficulty in keeping her own baby. There have been instances where the contracting individual has specified the sex of the baby as well, refused to take the baby if it was not normal and filed a suit against the surrogate saying she had broken the contract.

'There are practicalities such as the insemination, prenatal care, delivery and adoption procedures and social considerations including what and when to tell family friends and neighbours. The couple must be prepared for criticism from people who do not agree with what they are doing and they must be aware of the emotional strain that comes with such an unusual pregnancy.²

Generally, the surrogate is artificially inseminated with the sperm from the contracting father. In some cases the child is conceived' naturally.

The surrogate acts as a gestator or 'incubator'. However there is no comparison between ejaculate of the body and the body itself. A New Jersey Court opined that the time difference between producing semen and producing a child is enough to destroy the analogy. What surrogates sell is not their labour but their body itself and every act that the surrogate performs may be under the scrutiny of the contracting couple. She is never off-duty.

Rights of the Contracting Father are Paramount

The contracting couple adopts the baby soon after delivery so that they become legal parents of the child. Unlike adoption, a contract is signed before the baby is conceived. Surrogate contracts are usually written to favour the contracting father. Acting from a position of relative wealth, he hires a lawyer to assure pre-eminence of his interests not only over the surrogate but also over his infertile wife, whose consent is not typically required. It is the father to whom the baby must be delivered, and the primary concern of the contract is 'to make certain the child has the sperm and name of the buyer.'³

In surrogacy the rights of the child are almost never considered. Transferring the duties of parenthood from the birthing mother to a contracting couple is denying the child its claim against both the mother and the father.

Surrogacy Models

Two models have been described - the free market model and the prostitution model. Both see surrogacy as a job and imply the selling of service or other commodity. A contractual model leaves out the interests of infants, who are no contracting parties. Most meticulously worded surrogacy contracts cannot protect the surrogate mother's freedom, not only because of the current patterns of patriarchy, and not only because of non-volitional nature of the functioning of her body but also because of the control over the rearing-of the child.

It is simply not true that the surrogacy arrangement primarily benefits the infertile wife. The wife of the father of the child produced as a result of the surrogacy arrangement remains infertile.

Under the contract, the natural mother is irrevocably committed before she knows the strength of her bond with the unborn child. She never makes a totally voluntary, informed decision, for quite clearly any decision prior to the baby's birth 'is, in the most important sense, uninformed, and any decision after that, compelled by a pre-existing contractual commitment and the threat of a lawsuit, is less than totally voluntary.

An Unequal Bargain

The supposed benefits of surrogacy are created by a capitalist patriarchal society. It is assumed that there is an equal exchange - money paid for the service rendered. In reality the contract between the parties to surrogacy would not exist if the parties were equal. The woman must give more than her egg in order to gestate a child - an important gender difference. Within this framework the contract is always biased in favour of the financially secure male. The freedom of the surrogate mother is an illusion. The arbitration of rights hides central social and class issues which make surrogacy contracts possible.

In cases where the court decides 'in the best interest' of the child, the contracting couple is most likely to gain custody. The fact that a surrogate mother enters into a contractual agreement to give up her child is believed to make her an unfit mother. How could a good mother give up her child? Secondly, the contracting couple is likely to be financially more secure.

Women's Reproductive Rights Information Campaign in Britain is 'concerned about how technologies such as surrogacy would affect women in the Third World countries. Poor women in Africa, Asia and South America would be paid a pittance for the use of their wombs by Westerners who would not consider asking other Western women to do the same. Third World countries could become bases for manufacturing embryos.

References

1. Nelson Hilde Lindemann, Nelson James Lindemann: Cutting motherhood in two: some suspicions concerning surrogacy. In: Holmes Helen Bequaert, Purdy Laura (Eds.): *Feminist perspectives in medical ethics*. New York: Hypatia Inc., 1992.
2. Downie Susan: *Baby making - the technology and ethics*. London: The Bodley Head, 1988.
3. Overall Christine: *Ethics of human reproduction* Boston: Allen and Unwin, 1987.

Commercial Surrogacy: A Contested Terrain in the Realm of Rights and Justice

Sarojini Nadimpally, Sanaha Banerjee, Deepa Venkatachalam

Abstract

Commercial surrogacy has emerged in recent years as a volatile site in the encounter among gender, technology, and society; one that is blurring the boundaries not just of the body, but also of feminist praxis. In India, a country that has become a favoured global destination for low-cost, high-tech reproductive tourism, the practice of commercial surrogacy is generating polarised representations: either as a win-win situation or a race-to-the-bottom. Given the extreme vulnerabilities of a vast majority of poor Indian women due to exclusion and marginalisation in labour and job markets, patriarchal social and family structures, and low educational levels, the immediate financial gain through surrogacy assumes significant motivation. Though the fertility market is based on the principles of capitalist economy, its wider ramification both within the country and beyond is yet to unfold. Commercial surrogacy needs to be analysed along the lines of women's reproductive health issues, and within the larger context of rights and justice.

This paper examines the phenomenon of surrogacy as an industry in India and provides an overview of its operations. An understanding of this industry will be strengthened through an analysis of the regulatory framework in India, and within the broader Asian context. The paper focuses on the way the ideology of family and patriarchal notions of kinship act as drivers for the surrogacy industry, as well as on the interface between new technologies and old social structures that construct families. It then moves toward an assessment of the role of women vis-à-vis the conception of surrogacy as a form of labour. As conclusion, this paper puts forward reflections on the recent regulatory move to ban commercial surrogacy in India and questions whether such a ban serves as a panacea as far as surrogacy is concerned, whereby women's bodily integrity is at the core, beyond the narrow commercial versus altruistic binary.

Surrogacy: A Brief Background

Surrogacy arrangements have been under scrutiny from medical practitioners, researchers, academics, policymakers, and the mass media for the ways such arrangements take into consideration the role of the surrogate, the use of technology, and the future of the child born from the arrangement. In the past two decades, the phenomenon of commercial gestational surrogacy, as it has emerged in India, has had a trajectory distinct from how the practice flourished in the global North.

Up until the 1980s, before the widespread use of in vitro fertilisation (IVF), genetic or traditional surrogacy was a common practice globally. However, in the 1980s, a spate of cases hit the global North in which women who acted as surrogates refused to part with the children after giving birth, and staked a claim to their custody. Most notable among such cases was the 1985 Baby M case in New Jersey. Even though the custody of the child was eventually given to the father in the "best interest of the child," the case galvanised complex debates around the validity of surrogacy contracts, the ethics of arranging surrogacy commercially, how surrogacy amounts to "baby selling," and to commodification of women's reproductive abilities and objectification of their bodies.¹ The potential of conflict between intending

parents and women who act as surrogates and the possible exploitation of surrogates were also serious concerns that emerged.² Consequently, governments in many countries of the global North enacted laws that prohibited commercial surrogacy. For example, following the 1984 report of the Committee of Inquiry into Human Fertilisation and Embryology or the Warnock Report, the United Kingdom prohibited commercial surrogacy through the Human Fertilisation and Embryology Act of 1990.³ In France, surrogacy has been illegal since 1991. Other European countries like Germany, the Netherlands, and Spain also prohibit surrogacy.⁴

India offers a conducive environment for the development of surrogacy as an industry, mainly due to a willing and enabling private sector and the lack of regulation. Add to this the comparatively lower costs, less waiting time, availability of women willing to be surrogates, and the extra services such as close monitoring of the surrogates. Infrastructure and medical expertise comparable to international standards and a wide network of intermediaries have together with the above factors facilitated the further expansion of the industry, not only locally, but also internationally.

Definitions

Surrogacy

An arrangement in which a woman agrees to undertake a pregnancy with the intention to carry it to term and hand over the child to the parents for whom she is acting as a surrogate.

Genetic or Traditional Surrogacy

Surrogacy through the use of the eggs of the surrogate. This may be done through coitus or artificial insemination of the sperm.

Gestational Surrogacy

Surrogacy done through in vitro fertilisation (IVF), where an embryo is transferred into a woman who will gestate it. In such a case, the ova and sperm could belong to the commissioning parents, or donor gametes maybe used. Gestational surrogacy is a more invasive technique than traditional surrogacy, since it requires embryo transfer, and heavy medication for inducing the pregnancy.

Altruistic Surrogacy

The surrogate accepts no monetary compensation for carrying the pregnancy to term.

Commercial Gestational Surrogacy

Involves monetary compensation to the woman who agrees to act as a surrogate. This is widely practiced in India.

The Surrogacy Industry and Market

Sunder Rajan cautions that there is a need to retain focus on larger processes and structures driving global body economies that impinge upon women's health and rights.⁵ In contextualising commercial surrogacy, this paper scrutinises the larger systems within which it is located and operationalised.

In a globalised market, where women's reproductive labour is increasingly getting commercialised, surrogacy has assumed the proportion of an industry and forms a substantial part of the larger and expanding fertility industry and "reproductive tourism." In recent years, the sharp growth in commercial surrogacy in India has drawn much attention and raised several concerns. Lawyer Apurva Agarwal claimed, in a 2008 article by the Indo-Asian News Service, that commercial surrogacy was a USD445 million industry in India, while Namita Kohli, writing for The Hindustan Times in 2011, estimated the commercial surrogacy market at over 2000 crore rupees or about USD298 million. India has been among the most favoured destinations for surrogacy owing to the comparatively low costs, minimum waiting

time, absence of a regulatory framework (until 2012, after which certain restrictions and criteria were imposed with regard to commissioning couples accessing surrogacy arrangements), “easy availability” of surrogate women, and a wide network of clinics that offer the use of Assisted Reproductive Technology (ART), primarily in the private healthcare sector, that boast of “world class” infrastructure and facilities.

The growth of commercial surrogacy as an industry was not restricted to ART clinics alone. The potentially large overseas market has also motivated the expansion of the industry in smaller cities and towns. The business of reproductive tourism in India thus involves a spectrum of global and local intermediaries or third party agencies. These emerging players include a wide array of organisations catering to clientele both at the national and international levels. They range from ART consultants, medical tour operators, surrogacy agents, the hospitality industry, law firms, and tourism departments to other organisations specialising in reproductive tourism promotion.⁶ Employing aggressive promotional tactics to attract clients, especially from overseas, these players offer competitive incentives, packages, and deals, in providing a quality surrogates and a “seamless” process. A large informal network of agents across the country recruit women to act as surrogates and also ensure supervision, monitoring, and surveillance during the course of their surrogate pregnancies, often in surrogacy hostels.

Commercial surrogacy is often portrayed as a win-win situation, seen to give desperate and infertile parents the child they want and poor surrogate women the money they need. However, it is important to consider commercial surrogacy’s location in the contemporary encounter of globalisation, technology, labour, and gender, in understanding the phenomenon in a holistic manner.

The study *Birthing a Market: A Study on Commercial Surrogacy* (2012) by the Sama Resource Group for Women and Health reveals that current operations in the surrogacy industry are unfavourable to surrogates who occupy the lowest rung of the industry. A woman must be married, with biological children (“proven fertility”), and must have her husband’s consent to be a surrogate. For surrogacy, the more invasive IVF Embryo Transfer (ET) is preferred over Intrauterine Insemination (IUI), in the interest of severing all biological links between the surrogate and the child (imagined as the potential source of possible conflicting claims over the child in the future). Surrogates have little to no information about multiple IVF ET cycles, and embryo implantation (and possible foetal reduction), or the likelihood and implications of a caesarean section delivery.

Further, the surrogates’ lifestyles are monitored by various actors through frequent check-ups, repeated phone calls and visits from the commissioning parents, and surprise visits by agents. Surveillance is heightened in surrogate hostels. The surrogates are asked to refrain from having any sexual relations with their husbands preferably for the period of the pregnancy but particularly in the beginning, to ensure that conception is through the implantation of the embryos. Surrogates are asked to consume only home-cooked food and to increase intake of fruits, juice, nuts, and others. They are also asked to not exert themselves physically, with demands to minimise household work, avoid working outside their homes, or even going out during the last three months of the pregnancy. These demands regarding surrogates’ diet and mobility are often contrary to the surrogates’ needs or comforts, and may be adhered to, albeit reluctantly. Surrogacy arrangements currently regulate the lifestyle of the surrogate her sexual and physical activity, mobility, and diet, for example but not other important areas like the maximum number of surrogacies and the interval between surrogacies.

The surrogate relies entirely on the agent or the doctor for information regarding the surrogacy arrangement, including the payment process, drugs, and procedures. Her ability to negotiate is severely constrained. She signs a contract that is drawn up by the intended parents invariably in English, which is often not explained to her adequately. She is not provided with any legal counsel, or any counselling for her emotional and psychological needs. The health risks to mother and child from the drugs and ART procedures are both under-researched, and in the case of surrogacy, under-communicated. It is worth

asking what the nature of “informed consent” is in such a situation. Post-delivery, the surrogate must relinquish the child but has no control over the terms of relinquishment; for instance, she usually cannot breastfeed the child.

There is inadequate post-delivery follow up and care. The amount and pattern of payment is variable. The commission of the surrogacy agent may be deducted from the fees of the surrogate and this is not always clarified in advance. Thus, the role of the surrogate, her fees, and her contribution are absent in the scope and discussion of the surrogacy arrangement. Surrogate mothers are recruited and socialised to be part of such arrangements, structured in a manner that allows them little or no control.

Feminists argue that the surrogacy industry promotes exploitation as it is based on a neoliberal market model. Emphasising that cross-border trade is fundamentally based on economic disparity, Deborah Spar talks about the skewed choices that lead women who populate the lower ranks of the labour market to opt for surrogacy, and yet the bulk of the profits go mostly to brokers.⁷ Spar argues that concerns regarding global inequality have also been voiced in some cases like the garment industry and environmental arbitrage. However, those cases have led to regulation. According to Spar, state authority should be wielded to negate the possible ill-effects of surrogacy; prohibition, instead, would result in driving the practice to another region or even underground. As commercial surrogacy has flourished in India, so have the various ethical, social, and legal dilemmas arising out of it.

The current global traffic in body parts, their renting and selling, is unprecedented and has generated new ways of commodifying the human body and commercialising human labour. This has resulted in new and complex ethical, legal, political, and socio-cultural challenges.⁸ With surrogacy, reproductive materials and organs have assumed an independent and individualised existence, becoming the property of the person selling them; yet, we also find that the physical and social attributes of the seller affect the price and saleability of these materials. Both objectification and personification are parallel processes at play here. Users may seek surrogates or donor gametes from a particular religious background, just as they may want male or able bodied embryos to be selected for implantation. Sama’s study *Constructing Conceptions: The Mapping of Assisted Reproductive technologies in India* (2010) confirms that India’s fertility industry is mediated by class, caste, religion, gender, and other identities, and operates in an environment that leaves much to be desired in terms of access, equity, and justice.

In a new industry that is generating new conflicts, the regulatory framework is engaged in a process of defining and codifying what ethical conduct should look like in this industry. In this broader context, this paper probes into ideas that are gaining prominence and analyses the trajectories they traverse.

Regulating Surrogacy: Indian, Asian, and Global Contexts

Within the larger milieu of ART, surrogacy was sought to be regulated in India since the early 2000s. The Indian Council of Medical Research under the Ministry of Health and Family Welfare formulated the National Guidelines for Accreditation, Supervision, and Regulation of ART Clinics in India in 2005. These Guidelines, however, were not legally binding and meant to act literally as a guide for the clinics, which were expected to voluntarily follow them. ART clinics could not be held accountable for violation or non-adherence to provisions in the Guidelines, thus necessitating legislation to bring the operations of ART Clinics under the ambit of the law. The Council formulated a draft Assisted Reproductive Technology (Regulation) Bill first in 2008, which was subsequently updated in 2010, 2013, and 2014. In the original version, surrogacy remained open to all individuals regardless of their marital status. However, since the 2010 version, the draft laws have located surrogacy within the ambit of heterosexual marriage.

Further, in response to the growing anxiety around the rising transnational surrogacy arrangements in the country and on citizenship issues of children, the Ministry of Home Affairs issued new visa guidelines for

foreigners in July 2012. A new “medical” visa category was introduced for seekers of surrogacy who were instructed also to produce an affirmation from a competent authority in their home country or their embassies that surrogacy was recognised and that the child or children born out of surrogacy would be allowed to go back with the commissioning parents from India.

In 2015, however, the government tightened control over transnational surrogacy and stopped the issuance of visas for the purpose of commissioning a surrogacy altogether to foreigners.⁹

A central issue with regard to transnational surrogacy has been the legal and political ambiguities in determining the citizenship of children born out of such arrangements. In India, the two most important cases involving citizenship issues adjudicated by the Supreme Court involved Japanese (Manji Yamada vs. Union of India) and German (Jan Balaz vs. Union of India) commissioning parents. The German case is still pending at the Supreme Court. A brief overview of the Baby Manji case is presented here to outline the complexities that can arise in transnational surrogacy arrangements, including but not limited to issues of citizenship.

Japanese couple Ikufumi and Yuki Yamada travelled to India in late 2007 to hire a surrogate mother to bear a child for them. A surrogacy contract between the Yamadas and Pritiben Mehta, a married Indian woman with children, was agreed upon through a clinic in Gujarat. An embryo from Ikufumi Yamada’s sperm and an egg harvested from an anonymous Indian woman (a Nepalese donor in some reports) was then implanted into Mehta’s womb. In June 2008, the Yamadas divorced, and a month later Baby Manji was born to the surrogate mother. Although Ikufumi wanted to raise the child, his ex-wife did not. Suddenly, Baby Manji had three mothers the intended mother who had contracted for the surrogacy, the egg donor, and the gestational surrogate and a biological father. Yet, legally she had none. Both the parentage and the nationality of Baby Manji could not be worked out under existing definitions of family and citizenship in the Indian and Japanese laws. The circumstances soon evolved into a legal and diplomatic crisis.

The Japanese Civil Code recognises only the woman who gives birth to a baby as the legal mother and the guardian. In this case, the woman who gave birth to Baby Manji was Indian, so the baby was not entitled to a Japanese passport. Because Indian laws do not address commercial surrogacy, the genetic parents of babies born via surrogacy are required to adopt them. While Yamada should have been able to adopt Baby Manji because he was the genetic father, this did not happen as India’s Guardians and Wards Act of 1890 does not allow single men to adopt baby girls. Yamada could not file for an Indian passport for Manji, because although the clinic document mentioned him as the father, there was uncertainty as to who the mother was. Based on this and after much persuasion, the regional passport office issued Baby Manji an identity certificate as part of a transit document, paving the way for a travel visa to Japan. It was the first such identity certificate issued by the Indian government to a surrogate child born in India. It also gave Baby Manji’s paternal grandmother her custody in the absence of the genetic father. The Japanese Embassy issued the three-month-old a one-year visa on humanitarian grounds, which facilitated the baby’s entry into Japan with her Japanese grandmother. Japanese authorities stated at that time that Baby Manji could become a Japanese citizen “once a parent-child relationship has been established, either by the man recognising his paternity, or through his adopting her.” However, Baby Manji’s legal status in Japan after the expiry of her humanitarian visa in October 2009 is not known.

Baby Manji’s case demonstrates the vulnerability of the child who is rendered a “legal orphan” at birth, irrespective of the presence of people with whom she has genetic/biological ties. It is interesting how law often fails to keep up with technological advances that necessitate “novel” regulatory mechanisms. Surrogacy thus foregrounds old conventional questions around social citizenship, while raising new debates of economic participation and legal political citizenship. It transforms the very construct of social

citizenship itself and expands it further to accommodate larger debates about transnational transactions and the evolving care economy.¹⁰

In the Asian context, India and Thailand have been the most prominent centres for transnational surrogacy. The most prominent issue of contention has been the fact that women from marginalised socio-economic contexts in the developing world were acting as commercial surrogates for commissioning parents from developed countries, mediated by an “industry.” However, there has been a multiplicity of legal approaches towards the phenomenon of surrogacy in general, and transnational surrogacy in particular. The table below presents the legal scenarios regarding surrogacy in Asian countries for which information is available.

LEGALITY OF SURROGACY IN ASIA	
	Country
Surrogacy Not Legal	Afghanistan, Bahrain, Bangladesh, Cambodia, China, Indonesia, Jordan, Kuwait, Lebanon, Malaysia, Maldives, Nepal, Oman, Qatar, Saudi Arabia, Tajikistan, Thailand, Turkey, Turkmenistan, United Arab Emirates, and Yemen
Only Altruistic Surrogacy Legal	Hong Kong, India, South Korea, and Vietnam
Surrogacy Legal	Armenia, Georgia, Israel, Kazakhstan, Kyrgyzstan, and Ukraine
No Laws/Regulations	Azerbaijan, Japan, Pakistan, Philippines, and Singapore

Source: A compilation of the sources of information that forms the basis of this classification is given in the Appendix.

This establishes that the prevalent positions by countries vis-à-vis commercial surrogacy is “not legal” in the Asian context, with recent moves by countries considered “hubs” towards a prohibition on commercial transnational surrogacy. While India tightened control over visa regulations for foreigners commissioning surrogacy in 2012, the Thai government banned transnational surrogacy in 2015. The controversial case of an Australian couple abandoning one of the twin children born out of surrogacy in Thailand, while taking one of the twins along, led to this.¹¹ The child who was abandoned with the surrogate mother was born with Down’s Syndrome, while the other twin was healthy.

The stricter visa guidelines for foreigners commissioning a surrogacy in India exclude homosexual, single, and unmarried people. Given this scenario, many Indian clinics opened satellite centres in neighbouring Nepal, where Indian women travelled to act as surrogates for homosexual, single, and unmarried foreigners. This was brought to the fore with the tragic earthquake in Nepal in April 2015. There were reports of Israel organising airlifts for babies born out of surrogacy to its citizens through Indian surrogates, who, however, were left unattended amidst the destruction caused by the earthquake.¹² Subsequently, the Supreme Court of Nepal ruled against commercial surrogacy in the country in August 2015, and it was followed by a Cabinet decision of the Nepali government to formally ban the practice in September 2015.¹³

In the global context, some efforts have been initiated by The Hague Conference on Private International Law.¹⁴ In 2010, the growing problem of international surrogacy arrangements was discussed and “the complex issues of private international law and child protection arising from the growth in cross-border surrogacy arrangements” was acknowledged. The Council suggested that the private international law questions relating to international surrogacy arrangements be reviewed and the connections between international surrogacy cases and the 1993 Convention on Intercountry Adoption be discussed. A Special Commission noted that the number of international surrogacy arrangements was increasing rapidly and expressed concern over the uncertainty surrounding the status of many children born as a result of these arrangements. It was also recommended that The Hague Conference should carry out further study of the legal issues surrounding international surrogacy.

Ideology of Family and Kinship as Industry Drivers

To understand the appeal and context in which ART is used and commercial surrogacy is being practised, the social institution of the family, including the perceived need for giving birth and taking care of children, needs careful examination. The traditional family is constructed as a gender-structured, heteronormative, and procreative unit. More important is the universal connotation that accompanies this understanding. Women’s identification with their childbearing and childrearing duties is at the heart of hetero-patriarchal culture. The notion of motherhood as natural, and consequently understood as compulsory, has to be located in the pervasive ideology of family which holds that the stereotypical nuclear family is the universal social unit. The family has been accorded material and ideological privilege by society, which is evident from the high expectations of marriage and family, normalised in our cultures. While infertility in women is perceived as an unnatural condition which leaves women’s lives unfulfilled, male infertility is symbolic of emasculation. The pathological identification of infertility and the practice of commercial surrogacy are lodged in this ideological context. Yet another need for understanding family as an essentially procreative unit can also be located in the economic arrangement it embodies. Securing family wealth through inheritance is a strong consideration in reproduction across cultures. In social and political philosophy, reproduction within heterosexual and monogamous marriages is understood as the primary mode through which private property is held and social classes created and sustained.¹⁵

In the triad of family, marriage, and property, kinship through genealogy holds primacy. However, the use of gamete donors and the process of gestational surrogacy poses interesting challenges to this idea of kinship defined through genealogy. The idea that kin relations are established through genealogical relations must be located in the fact that the “family is not only an active agent of social control; it is also an active agent of social placement.”¹⁶

The idea of “designer babies,” increasingly visible in the demand for specific eggs/gamete on the basis of caste, class, race, and other criteria reflects how kinship and identity are also understood through community and one’s position in these social hierarchies. IVF treatment makes possible the securing of such bonds of belonging, which is also one of the reasons for boosting the industry and has also led to fewer reservations about surrogacy where the surrogate can be considered irrelevant.

According to Helena Ragone, “It has become increasingly clear that ‘biological’ elements have primarily symbolic significance [whose] meaning is not biology at all.”¹⁷ To illustrate the contingent nature of defining what constitutes the biological, Nivedita Menon gives the example of two diametrically opposite arguments that are made by doctors in the ART clinics.¹⁸ In the case of gestational surrogacy, the commissioning parents are told that the baby is not related to the surrogate in any way. Here, the understanding of the biological is reduced to DNA and genes. However, in case of a parent who is carrying a foetus she intends to raise, but fertilised by a donor egg, she is reassured that genes are a small component of the child’s constitution, because as the foetus grows, every cell is built out of the

gestational mother's body, thus making her the biological mother. Here, Menon makes it clear that the all-determining biology is being made up by doctors as they go along.

In the use of ART, Amrita Pande posits that challenges to more hegemonic notions of kinship take shape through the redefinition of the blood tie.¹⁹ The use of blood and human substance from parents, donors, and surrogates complicates the way the intertwined nature of the blood tie as a marker of identity is understood. By breaking down the reproductive process, not only in terms of the distinct components of gametes and gestation but also in taking it beyond the ambit of heterosexual marriage through involvement of donors and surrogates, the mother-child tie is redefined through gestation where the surrogate is only thought to be providing a service whereas parentage lies with others.

While bringing women's reproductive labour outside the family, gestational surrogacy also pushes a new understanding of masculinities. This aspect is illustrated poignantly by Rita, a surrogate (interviewed as part of Sama's research in 2012), when she joked about the "emasculatation" of husbands. Rita said her own husband had no contribution to the surrogate pregnancy, has no sexual relations with her while she is away, and has to take care of the children and cook. The intended father has no contact or relationship with her or the child throughout the pregnancy, thus demonstrating to her the "minimum contribution by men" in the process. Another surrogate, Parvati argued that "the role of the penis has been taken over by medicine and technology," implicitly reiterating her own contribution to the process.

The discourse around surrogacy is thus not strictly about biology/naturalness, as can be seen through inconsistent arguments that deploy the logic of the "nature-nurture" binary, or in the case of a surrogate and her reproductive labour.

Beyond the child born out of surrogacy, kinship relations are also forged in interesting ways among the people involved in a surrogacy process. In the overall framework of a commercial gestational surrogacy, the surrogate mother is often construed as an indispensable yet a "disposable" actor.²⁰ Pande observes that surrogates' narratives often reflect their belief that their relation with the commissioning couple/mother would continue even after the birth.²¹ Often the idea of their reciprocal involvement in each other's lives or association like any other family member is based variously on fantasy or reality of existing involvement. Throughout her ethnographic work, Pande shows how surrogates were able to construct kinship ties with women cutting across caste, religion, class, and national boundaries. She insightfully argues, "unlike in textbook kinship models, everyday forms of kinship seem to be open to manipulations and transformations. They offer new possibilities for understanding how relatedness may be composed of various components shared substance, shared company and the continuous labour of women."²²

New Technology, Old Structures

With their ability to delink reproduction from sex, ART creates new forms of parenthood and family that were not possible before. As such, single people and queer individuals and couples can now use ART to have biologically related children. It can be argued that ART privileges "procreative intent" over the narrow idea of biology (indeed they are interpreting and defining biology); this is how conflicting claims of multiple parents made possible by these technologies can be and are settled, most notably, through the law. This section is an exploration of the following issues: What is the potential in ART for the subversion of the heterosexual family? Does ART serve to pluralise, even democratise, the family and kinship, or do they merely circumscribe it, reinforcing and re-legitimising traditional formats? Or is it a bit of both?

The potential of ART in subverting the hetero-normative structure of the family by queer couples has been variously contested. By opening up the institution of family to homosexual partners, are we enhancing the scope and meaning of sexual and reproductive rights, and challenging traditional gender roles, or is it simply a need for recognition that dilutes such a challenge precisely for the desire to be in

such institutions and reinforce their “natural” and normal status? Cheshire Calhoun argues for an inclusive definitional framework for what is understood and legitimised as “family” and expanding it beyond heterosexual privilege. The inclusion of queer people in legal structures from where they have been historically outlawed for their “deviant nature” has become a possibility through ART. Moreover, creating families in alternative ways also includes the potential to provide alternatives to the conventional family form. And thus, “centred within a liberatory lesbian and gay politics, the bid for access to the family is the bid for the right to exercise definitional authority with respect to the family.”²³

However, body economies (including the surrogacy industry), despite their subversive potential to reconfigure social structures of patriarchy, gender, caste, class, and race, often get attuned to those traditional structures. Surrogacy through ART lies on the same spectrum as other phenomena that involve the intimate use of the body and its parts. In the context of one such phenomenon, organ donation, Lawrence Cohen highlights how caste and community have come to matter in how families choose organ donors and sellers in ways they hitherto had not.²⁴ Similarly, some people may seek surrogates or donor gametes from a particular religious background, just as they may want male or able-bodied embryos to be selected for implantation. Sama’s 2010 research, as discussed earlier in the paper, confirms this. Similarly, the surrogacy industry serves to re-inscribe ascriptive identities in sometimes predictable and sometimes unpredictable ways.

From Sama’s research, as well as other studies that document accounts of surrogates’ subjectivities, it is clear how notions of love and sacrifice play a very important role in decisionmaking. Surrogates often say they are acting “out of love” for their own children and to be able to give them a better future through entering into surrogacy arrangement. In fact, the distinction between “altruistic” and “commercial” surrogacy does not stand up to scrutiny, because commercial surrogates feel altruistically about what they do as well, and altruistic surrogacies could involve transactions, material and otherwise, especially when we consider that altruistic surrogacies occur within family and kinship networks, which are transactional in nature.

Further, the industry employs new and old patriarchal notions of womanhood, motherhood, gender, bodies, and labour. Since ART clinics employ a conscious marketing strategy that glorifies motherhood for women, feminists have criticised the industry for being patriarchal and capitalist, and for cashing in on the pressure on women to be mothers. Socially, the value accorded to biological parenthood within heterosexual marriage is far superior to the value accorded to voluntary childlessness, adoption, or alternative family/kinship structures. At least thus far in India, the practice of assisted reproduction is overwhelmingly geared towards reinforcing the heteropatriarchal family, by restoring the linear progression from heterosexual marriage to biological parenthood. Amrita Pande argues that the surrogate is socialised to be a “motherworker” in a way that her status as a mother is an insidious disciplining mechanism that undermines her status as a worker.²⁵ Saravanan argues that the most important criteria for choosing surrogates is their submissiveness to the demands of doctors and intended parents; clinics prefer women who are on the edge of poverty and not educated beyond the higher secondary level.²⁶ Additionally, the figure of the sex worker comes up a lot in interviews with agents, doctors, and surrogates; the sex worker is the “other,” the real “body-seller,” who serves to bolster the altruistic veneer of surrogacy for all involved.

Cohen discusses the State and the question of political form in the conversation on bioavailability from two standpoints: “operability” (the degree to which one’s belonging to and legitimate demands of the state are mediated through invasive medical commitment) and the medicalisation of politics.²⁷ Operability is a useful frame to employ in surrogacy. Given that women who act as surrogates are predominantly from marginalised sections of society,²⁸ there is a need to broaden the debate beyond rights for surrogates in the arrangement (though that is also urgent and needs intervention), to include larger issues of reproductive justice, autonomy, and oppression. Surrogates have very little autonomy over their own

pregnancies. They are from a class that has traditionally been targeted for population control, coercive, or incentivised tubectomies; have high maternal mortality and morbidity; and little access to healthcare that should be their entitlement. A longer-term, life-cycle view of the reproductive health of these women and its linkages with interrelated questions of livelihoods, nutrition, education, amongst others, helps to understand surrogacy not only in individual terms but also in the context of communal rights, state responsibility, political economy, and the conditions of women's labour under globalisation. Additionally, only women with "proven fertility" are eligible to be surrogates (can be seen as a prior operability that has marked its presence in their bodies through their identification as mothers). Often, women who start off doing egg donation later become surrogates, and maybe even surrogacy agents themselves. Clearly, this is a class that already has a medicalised and a highly gendered relationship with the state, and is characterised in public discourse as having "excessive passion and limited reason."

Surrogacy also flags important questions about reproductive autonomy and justice. If women's right to make reproductive choices with regard to contraception, abortion, and pregnancy is recognised, should we not also understand surrogacy as another choice for women to make? The idea of choice, however, is questioned by some feminists³⁰ given that women's control over their bodies is determined by social relations and power hierarchies. This is evident in the context of surrogacy arrangements, where denial of reproductive rights and autonomy are governed by private contracts, for instance, denial of surrogates' rights to abort, breastfeed, relinquish the child or children), among others.

A reproductive justice approach to surrogacy would therefore be one that looks to create structural changes, challenges the inherent power inequalities, and also accounts for reproductive oppression. However, the reproductive justice approach is not without its limitations. Alston Bailey recognises that a surrogate's life circumstances—housing needs, debt, illness, and disease—may make the health risks associated with contract pregnancy worth taking.³²

The decision to become surrogates is frequently founded in women's social conditioning to gendered roles of ensuring families' well-being.³³ Evidence also points to the industry's control and construction of information that women need to make an informed decision with regard to surrogacy.³⁴ Women are not provided clear and comprehensive information about the procedures that they will be undergoing and the implications and risks to their health and lives. For example, surrogate mothers would not be informed and would not know when they would undergo procedures for foetal reduction or would not have a choice about giving birth through caesarean procedure.³⁵ While commissioning parents have the right to demand abortion (if they wish to discontinue the arrangements, or in view of the detection of congenital abnormalities), the surrogate does not have the right to keep the child if she so wishes. Surrogate women thus have little or no say in decisions, including decisions about their own bodies.

Concerns surrounding surrogacy do not result only from a view of motherhood as sacrosanct and pure. Rather, a feminist engagement with surrogacy, as feminist Chayanika Shah puts it, is conflicted about "the disconcerting use of the language of 'rights' and 'choice' by the promoters of these businesses on behalf of women going in for these technologies" on the one hand, and "the assertion of rights over the body as a resource" on the other hand.³⁶

Labour in Surrogacy, Surrogacy as Labour

The debate over the use of the body is at the heart of the development and use of new biotechnologies. Oocytes donation, commercial surrogacy, contributions for stem cell research, and clinical trial participation are some of the ways in which people undergo biological processes, very often stimulated, or make bodily contributions either in exchange for money or in kind or as a promise for future treatment.

When considering the question of surrogacy as labour, it is important to map out and understand key patriarchal constructions, the logic of capital and market, and how they converge at various points. The

concept of labour has always been at the centre of feminist debates and theorisation. The classical concept of labour is that of a socially recognised, productive activity that operates on the principle of exchange in the present capitalist society. This understanding of labour, however, has to be located as a historical construction where the separation of home and family and its identification with a private sphere were created in opposition to labour outside the home and seen as the public sphere of all commercial activities and those establishing one as a citizen. This dichotomy was also seen to be the basis of sexual division of labour, accompanied by power organised both materially as well through accompanying ideology of “natural” gender roles and relations.

Feminist scholarship has noted the construction of this distinction with the advent of western capitalism and explained that the creation of this so-called unproductive realm of activity associated traditionally with women itself is a creation of capitalist economy, which has been crucial in sustaining capitalist relations of production.³⁷ Feminist critiques and activism have traversed a long path from critiquing its invisibilisation to its informalisation. Childbearing and childrearing have always been seen as part of the naturalised, non-commercial, and most of all, non-productive activity, often coloured by motherly love and nurturance.

Surrogacy has effectively destabilised the popular understanding of labour, where the separation of home and family and its identification with the private sphere was created in opposition to work outside home and seen as the public sphere of all commercial activities and those establishing one as a citizen. Surrogacy is not understood as formal wage work. The question that is at the heart of the debate is, What establishes this kind of labour as valuable and how much? Furthermore, does “surrogate” imply a patient, or worker, a participant, or an equal contracting party? Is she the mother/is she a mother? What is the basis of kinship and claim over the child and is there a hierarchy of bodily contribution itself?

In a bid to mobilise biological resources and participation for the needs of the industry and market, these technologies can also generate encounters that create friction with the existing social relations and hierarchies of gender, class, caste, and religion. Additionally, the possibilities of reproductive choices and decision-making with regard to children, family, and income can itself be a site for struggle over entitlements, recognition, self-perception, and membership in extended family networks and larger communities.

New markets for women’s labour under globalisation deploy women’s bodies in highly gendered and sexualised roles. While surrogacy pushes the limits of women’s labour from the private to the public and from care to work, the accompanying technological interventions in their bodies pose serious threats to their health due to the use of a large quantity of hormonal drugs and injections needed to sustain the surrogate pregnancy. Sama’s 2012 research shows that a surrogate’s informed consent is often not sought during the surrogacy process. Commercial surrogacy brings women’s reproductive labour into the market in an unprecedented manner and poses a challenge to ideological constructs of the family, to the perceived separation of the family from the market, and indeed to the very basis of kinship. In this scenario, women’s reproductive labour is being performed in a particular configuration. The nature of this labour changes when it transgresses these norms and enters the marketplace; to scrutinise the norms as well as the rationale governing this labour once it is commercialised; and at the same time to examine how the prevalent social norms and meanings are alternately negotiated and deployed.

It is important to understand that this subversion is located within an industry that is operating in the context of the increasingly liberalising economic policies of the State, of an established and flourishing privatised health sector, and of the availability of women’s cheap labour. On one level, the subversive potential lies in the fact that childbearing is considered as a commercial act, for which women are being remunerated. On the other, the challenges to the understanding of the biological basis of parentage and

kinship are severe since such arrangements break the linear links and create multiple parents based on the use of gametes, womb, and procreative intent each of which could be attributed to a different person.

However, in practice, what can be seen is that the conditions under which the surrogates perform this labour are often a mix of deployment of existing meanings of family and market at the same time to ensure a successful outcome. The dimension of exploitation is indicative in this work as the location of these women. According to Sama's 2012 study, most women who become surrogates and their spouses were employed in seasonal, irregular, low-paying, insecure, and informal jobs. Women were mostly engaged in informal garment work, factory work, domestic work, cooking, garment stitching, or other home-based work, or were not employed formally outside their household. Their spouses were engaged in work such as driving, cooking, and garment factory work.

In the context of the spectrum of body economies, the driving logic of capitalist production, according to Sunder Rajan, is that of creating "surplus health."³⁸ Furthermore, "health itself gets redefined into becoming something alienable and appropriable, a source of surplus value in a manner analogous to that by which labour became surplus labour under logics of industrial capital. Patients, in this calculus, have no meaning except as potential future consumers of therapy, leading to the imagination of patients as, always already, patients-in-waiting who are consumers-in-waiting."³⁹

In the case of surrogacy, such logic overlooks health as a shared necessity of both the surrogates and the commissioning parents. On the other hand, this logic also sustains the continuous production and pathologisation of infertility. To account for the present situation requires understanding the uniqueness of these forms as well as situating it in its shared characteristics of contractual, insecure, casual labour increasingly prevailing as the general form of labour globally. Thus, we need to better understand the linkages between technological development, innovation, and policy shifts in post-industrial economies on the one end, and multiple articulations of labour, risk, and fragmentation experienced in developing economies by those already part of global value chains through their participation in the workforce in other industries simultaneously.

Conclusion

Unpacking Bodily Integrity

Most recently in August 2016, the Government of India carved out a new proposed law with the sole focus on surrogacy. Surrogacy (Regulation) Bill 2016 emerged separately from the Draft ART Bill 2014 whose fate remains uncertain. The new Surrogacy Bill prohibits commercial surrogacy and allows only altruistic arrangements within "close relatives," where the surrogate will not receive any remuneration. Moreover, it limits access to surrogacy only for childless Indian heterosexual couples who have been married for five years. Such eligibility criteria are discriminatory towards all the other people who may want to access surrogacy but are now rendered ineligible unmarried couples, individuals who are single, and the queer community. Even for married couples who are infertile, a window of five years may seem arbitrary since a clinical diagnosis of infertility rests on the "inability of a sexually active, non-contracepting couple to achieve pregnancy in one year."⁴⁰

As a policy response, a ban runs the risk of creating black markets and further exacerbating the vulnerabilities of women who act as surrogates. In patriarchal societies, families can also be exploitative towards women who may be coerced to become surrogates for close relatives. Thus, the argument that commercial surrogacy is an exploitative arrangement, while altruistic surrogacy is not, does not stand on firm ground.

A pro-ban vs. anti-ban debate on commercial surrogacy tends to miss the larger picture of how gestational surrogacy using IVF is induced and how the surrogacy industry functions. Until the Bill is passed, it is

difficult to assess how it can safeguard the rights of women who act as surrogates in India, an issue that is much broader than just remuneration for surrogacy. It includes women's ability to make informed decisions regarding intrusive technological interventions in their bodies, their reproductive autonomy, their right to health, and control over their reproductive labour. Commodification and choice are enmeshed in a very complex way. For surrogates, earning a living by giving birth is closely linked to their own contexts where at a given time, surrogacy appears to be the best available option.⁴¹ The more pressing question is that of the right against exploitation, upholding their rights as workers in the surrogacy industry, ensuring informed consent, payment of wages, and legal guarantees for the same. Will banning commercial surrogacy address all these pressing issues?

In the regulation of ART, including surrogacy, "technology" is seen in isolation from women's voices. Sama's research has focused on the voices of women from both sides women who access infertility treatments as patients⁴² and also women who act as surrogates.⁴³ Both experience vulnerability and lack of bargaining power in a hyper-medicalised scenario. However, the latter is even more vulnerable since her experience is not just mediated by technology and medical practitioners but also by her economic deprivation and her location at the lowest tier of the surrogacy industry.

The phenomenon of surrogacy, regardless of whether it is commercial or altruistic, necessitates a broader unpacking of various concepts that have become a part of the feminist lexicon. One such conceptual trope is that of "bodily integrity." It must be unpacked to include scenarios where somebody's bodily rights are sought to be projected on others' bodies, especially when those others are more vulnerable and marginalised; even more so when such projections find transnational expression. Infertility treatment which piggybacks on a "right to procreation" presents a case in point when that right is sought to be realised through the bodies of egg and sperm donors, as well as commercial surrogates. Bodily integrity understood as opportunity, power, and rights must be problematised to factor in hierarchies of gender, race, caste, class, and ethnicity and those that arise from global politico-economic asymmetries.

Endnotes

- 1 Norma J. Wikler, *Society's Response to the New Reproductive Technologies: The Feminist Perspective*, *Southern California Law Review* 59, No. 5 (1986): 1043-57.
- 2 D. Kelly Weisberg, ed, *Applications of Feminist Legal Theory to Women's Lives: Sex, Violence, Work, and Reproduction*, (Philadelphia: Temple University Press, 1996).
- 3 Surrogacy UK. "Surrogacy in the UK: Myth Busting and Reform," Report of the Surrogacy UK Working Group on Surrogacy Law Reform, November 2015, accessed 23 September 2016, <https://www.kent.ac.uk/law/research/projects/current/surrogacy/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf>.
- 4 Hannah Flint, "Legal Situation of Surrogacy Explained," *The Telegraph*, 1 August 2014, accessed on 23 September 2016, <http://www.telegraph.co.uk/news/worldnews/asia/thailand/11006524/Legal-situation-of-surrogacyexplained.html>.
- 5 Kashik Sunder Rajan, *Biocapital: The Constitution of Postgenomic Life*, (Durham: Duke University Press, 2006).
- 6 Sneha Banerjee, "Emergence of the 'Surrogacy Industry'," *Economic and Political Weekly* 47, No. 11 (2012): 27-29. See also: Nadimpally Sarojini and Vrinda Marwah, "Body as 'Resource' in Surrogacy and Medical Research: New Frontiers and Dilemmas," in *Equity and Access: Healthcare Studies in India*, ed. P. Prasad and A. Jesani, (Oxford: Oxford University Press, 2016).
- 7 Debora L. Spar, *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*, (Cambridge: Harvard Business School Press, 2006).
- 8 Nadimpally Sarojini and Vrinda Marwah, "Body as 'Resource' in Surrogacy and Medical Research: New Frontiers and Dilemmas," in *Equity and Access: Healthcare Studies in India*, ed. P. Prasad and A. Jesani, (Oxford: Oxford University Press, 2016).

- 9 Press Information Bureau, Ministry of Health and Family Welfare, Government of India, "Law for Regulating Surrogacy," 2 December 2015, accessed 15 September 2016, <http://pib.nic.in/newsite/PrintRelease.aspx?relid=132218>.
- 10 Sama Resource Group for Women and Health, *Constructing Conceptions: The Mapping of Assisted Reproductive Technologies in India*, (New Delhi: Sama Resource Group for Women and Health, 2010).
- 11 Aukkarapon Niyomat, "Thailand Bans Surrogacy for Foreigners in Bid to End 'Rent-a-Womb' Tourism," Reuters, 19 February 2015, accessed 15 September 2016. <http://www.reuters.com/article/us-thailand-surrogacyidUSKBN0LO07820150220>.
- 12 Debra Kamin, "Israel Evacuates Surrogate Babies from Nepal but Leaves the Mothers Behind," *The Time*, 28 April 2015, accessed 15 September 2016. <http://time.com/3838319/israel-nepal-surrogates/>.
- 13 Embassy of the United States in Kathmandu, "Surrogacy Services Are Banned in Nepal," 14 June 2016, accessed 15 September 2016, [https:// np.usembassy.gov/u-s-citizen-services/local-resources-of-u-s-citizens/surrogacy-in-nepal/](https://np.usembassy.gov/u-s-citizen-services/local-resources-of-u-s-citizens/surrogacy-in-nepal/).
- 14 The Hague Conference on Private International Law, Preliminary Document No. 11 of March 2011 for the Attention of the Council of April 2011 on General Affairs and Policy of the Conference, (The Hague: Hague Conference on Private International Law, 2011), accessed 15 September 2016, <https://assets.hcch.net/docs/f5991e3e-0f8b-430c-b030-ca93c8ef1c0a.pdf>.
- 15 Michele Barrett and Mary McIntosh, *The Anti-social Family*, (London: Verso Books, 1980).
- 16 Andre Beteille, "The Reproduction of Inequality: Occupation, Caste, and Family," *Contributions to Indian Sociology* 25, No. 1 (1991): 3-28.
- 17 Helena Ragoné, "Surrogate Motherhood and American Kinship," in *Kinship and Family: An Anthropological Reader* ed. R. Parkin and L. Stone, (Oxford: Blackwell Publishing Ltd., 2004), 342-361.
- 18 Nivedita Menon, "The Disappearing Body and Feminist Thought," *Critical Encounters*, 19 February 2011, accessed 30 October 2014, [https:// criticalencounters.net/2011/02/19/the-disappearing-body-and-feministthought/](https://criticalencounters.net/2011/02/19/the-disappearing-body-and-feministthought/).
- 19 Amrita Pande, "'It May Be Her Eggs but It's My Blood': Surrogates and Everyday Forms of Kinship in India," *Qualitative Sociology* 32, No. 4 (2009): 379-397.
- 20 Amrita Pande, *Wombs in Labor: Transnational Commercial Surrogacy in India*, (New York: Columbia University Press, 2014).
- 21 Pande, "'It May Be Her Eggs but it's My Blood.'"
- 22 Cheshire Calhoun, *Feminism, the Family, and the Politics of the Closet: Lesbian and Gay Displacement*, (Oxford: Oxford University Press: 2000).
- 23 Lawrence Cohen, "Operability, Bioavailability, and Exception," in *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* ed. Aihwa Ong and Stephen J. Collier, (New Jersey: Wiley-Blackwell, 2005) 79-90.
- 24 Pande, "It may be her eggs but it's my blood."
- 25 Sheela Saravanan, "Transnational Surrogacy and Objectification of Gestational Mothers." *Economic and Political Weekly* 45, No. 16 (2010): 26-29.
- 26 Cohen, "Transnational Surrogacy and Objectification of Gestational Mothers."
- 27 Sama Resource Group for Women and Health, *Birthing a Market: A Study on Commercial Surrogacy*, (New Delhi: Sama Resource Group for Women and Health, 2012).
- 28 (Cohen 2005). "Transnational Surrogacy and Objectification of Gestational Mothers."
- 29 Janna C. Merrick, "Selling Reproductive Rights: Policy Issues in Surrogate Motherhood," *Politics and Life Sciences*, 8, No. 2, *The Politics of Surrogacy Contracts* (February 1990): 161-172.
- 30 Sama Resource Group for Women and Health, *Birthing a Market*.
- 31 Alison Bailey, "Reconceiving Surrogacy: Toward a Reproductive Justice Account of Indian Surrogacy," *Hypatia* 26, No. 4 (2011): 715-741.
- 32 Sama Resource Group for Women and Health, *Birthing a Market*.

- 33 See for example, Sama Resource Group for Women and Health, *Birthing a Market and Pande, Wombs in Labor*.
- 34 Sama Resource Group for Women and Health, *Birthing a Market*.
- 35 Chayinka Shah, "Regulate Technology, Not Lives: A Critique of the Draft ART (Regulation) Bill," *Indian Journal of Medical Ethics* 6, No.1 (2009): 32-35, accessed on 26 September 2016, <http://ijme.in/index.php/ijme/article/viewFile/433/787>.
- 36 Mies Maria, *Patriarchy and Accumulation on a World Scale: Women in the International Division of Labour*, (London: Palgrave Macmillan, 1998).
- 37 Kaushik Sunder Rajan, "Surplus Health, Clinical Trials and Access to Medicines: Structural and Conceptual Provocations," Presentation at the National Consultation on Regulation of Drug Trials, New Delhi, India, 26-27 September 2011.
- 38 Kaushik Sunder Rajan, "Surplus Health, Clinical Trials and Access to Medicines."
- 39 World Health Organization, "Infertility Definitions and Terminology," accessed 15 September 2016, <http://www.who.int/reproductivehealth/topics/infertility/definitions/en/>.
- 40 Sama Resource Group for Women and Health, *Birthing a Market*.
- 41 Sama Resource Group for Women and Health, *Constructing Conceptions*.
- 42 Sama Resource Group for Women and Health, *Birthing a Market*.

References

1. Bailey, Alison. "Reconceiving Surrogacy: Toward a Reproductive Justice Account of Indian Surrogacy." *Hypatia* 26, No. 4 (2011): 715-741.
2. Banerjee, Sneha. "Emergence of the 'Surrogacy Industry'." *Economic and Political Weekly* 47, No. 11 (2012): 27-29.
3. Barrett, Michele and Mary McIntosh. *The Anti-social Family*. London: Verso Books, 2015.
4. Beteille, Andre. "The Reproduction of Inequality: Occupation, Caste, and Family." *Contributions to Indian Sociology* 25, No. 1 (1991): 3-28.
5. Cohen, Lawrence. "Operability, Bioavailability, and Exception." In *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* edited by Aihwa Ong and Stephen J. Collier, 79-90. New Jersey: WileyBlackwell, 2005.
6. Collier, Jane F., Michelle Z. Rosaldo, and Sylvia Yanagisako. "Is There a Family?: New Anthropological Views." In *Rethinking the Family: Some Feminist Questions* edited by B. Thorne and M. Yalom, 25-39. Longman: New York, 1982.
7. Embassy of the United States in Kathmandu. "Surrogacy Services Are Banned in Nepal." 14 June 2016. Accessed 15 September 2016. <https://np.usembassy.gov/u-s-citizen-services/local-resources-of-u-s-citizens/surrogacy-innepal/>.
8. Flint, Hannah. "Legal Situation of Surrogacy Explained." *The Telegraph*. 1 August 2014. Accessed on 23 September 2016. <http://www.telegraph.co.uk/news/worldnews/asia/thailand/11006524/Legal-situation-of-surrogacy-explained.html>.
9. Hague Conference on Private International Law. Preliminary Document No. 11 of March 2011 for the Attention of the Council of April 2011 on General Affairs and Policy of the Conference. The Hague: Hague Conference on Private International Law, 2011. Accessed 15 September 2016. <https://assets.hcch.net/docs/f5991e3e-0f8b-430c-b030-ca93c8ef1c0a.pdf>.
10. Indo-Asian News service. "Surrogacy a \$445mn Business in India." *dna India*, 25 August 2008. Accessed on 15 September 2016. <http://www.dnaindia.com/mumbai/report-surrogacy-a-445-mn-business-in-india-1185602>.
11. Kamin, Debra. "Israel Evacuates Surrogate Babies from Nepal but Leaves the Mothers Behind." *The Time*, 28 April 2015. Accessed 15 September 2016. <http://time.com/3838319/israel-nepal-surrogates/>.
12. Kohli, Namita. "Moms Market." *Hindustan Times*. 12 March 2011. Accessed 15 September 2016. <http://www.hindustantimes.com/india/moms-market/story-4V8X4loEqLMRO82K3x50XI.html>.
13. Menon, Nivedita. "The Disappearing Body and Feminist Thought." *Critical Encounters*, 19 February 2011. Accessed 30 October 2014. <https://criticalencounters.net/2011/02/19/the-disappearing-body-and-feministthought/>.
14. Merrick, Janna C. "Selling Reproductive Rights: Policy Issues in Surrogate Motherhood." *Politics and Life Sciences*, 8, No. 2, *The Politics of Surrogacy Contracts* (February 1990): 161-172.

15. Mies, Maria. *Patriarchy and Accumulation on a World Scale: Women in the International Division of Labour*. London: Palgrave Macmillan, 1998.
16. Niyomat, Aukkarapon. "Thailand Bans Surrogacy for Foreigners in Bid to End 'Rent-a-Womb' Tourism." Reuters, 19 February 2015. Accessed 15 September 2016. <http://www.reuters.com/article/us-thailand-surrogacyidUSKBNLO07820150220>.
17. Pande, Amrita. *Wombs in Labor: Transnational Commercial Surrogacy in India*. New York: Columbia University Press, 2014. _____. "It May Be Her Eggs but It's My Blood': Surrogates and Everyday Forms of Kinship in India." *Qualitative Sociology* 32, No. 4 (2009): 379-397.
18. Points, Kari. "Commercial Surrogacy and Fertility Tourism in India: The Case of Baby Manji." *Institutions in Crisis*. Durham: Duke University, 2012. Accessed 15 September 2016. <https://web.duke.edu/kenanethics/CaseStudies/BabyManji.pdf>.
19. Press Information Bureau, Ministry of Health and Family Welfare, Government of India. "Law for Regulating Surrogacy." 2 December 2015. Accessed 15 September 2016. <http://pib.nic.in/newsite/PrintRelease.aspx?relid=132218>.
20. Ragoné, Helena. "Surrogate Motherhood and American Kinship." In *Kinship and Family: An Anthropological Reader* edited by R. Parkin and L. Stone, 342- 361. Oxford: Blackwell Publishing Ltd., 2004.
21. Ruggeri, Kai, Ladislav Záliš, Christopher R. Meurice, Ian Hilton, Terry-Lisa Ly, Zorana Zupan, and Saba Hinrichs. "Evidence on Global Medical Travel." *Bulletin of the World Health Organization* 93, No. 11 (2015): 785-789. Accessed 15 September 2016. <http://www.who.int/bulletin/volumes/93/11/14-146027/en/>.
22. Sama Resource Group for Women and Health. *Birthing a Market: A Study on Commercial Surrogacy*. New Delhi: Sama Resource Group for Women and Health, 2012. _____.
 - a. *Constructing Conceptions: The Mapping of Assisted Reproductive Technologies in India*. New Delhi: Sama Resource Group for Women and Health, 2010.
23. Saravanan, Sheela. "Transnational Surrogacy and Objectification of Gestational Mothers." *Economic and Political Weekly* 45, No. 16 (2010): 26-29.
24. Sarojini, Nadimpally and Vrinda Marwah. "Body as 'Resource' in Surrogacy and Medical Research: New Frontiers and Dilemmas." In *Equity and Access: Healthcare Studies in India* edited by P. Prasad and A. Jesani. Oxford: Oxford University Press, 2016.
25. Shah, Chayanika. "Regulate Technology, Not Lives: A Critique of the Draft ART (Regulation) Bill." *Indian Journal of Medical Ethics* 6, No.1 (2009): 32-35. Accessed on 26 September 2016. <http://ijme.in/index.php/ijme/article/viewFile/433/787>.
26. Spar, Debora L. *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. Cambridge: Harvard Business School Press, 2006.
27. Sunder Rajan, Kaushik. "Surplus Health, Clinical Trials and Access to Medicines: Structural and Conceptual Provocations." Presentation at the National Consultation on Regulation of Drug Trials, New Delhi, India, 26-27 September 2011. _____. *Biocapital: The Constitution of Postgenomic Life*. Durham: Duke University Press, 2006.
28. Surrogacy UK. "Surrogacy in the UK: Myth Busting and Reform." Report of the Surrogacy UK Working Group on Surrogacy Law Reform, November 2015. Accessed 23 September 2016. <https://www.kent.ac.uk/law/research/projects/current/surrogacy/Surrogacy%20in%20the%20UK%20Report%20FINAL.pdf>.
29. Warner, Judith. "Outsourced Wombs." *New York Times*, 3 January 2008. Accessed 15 September 2016. http://opinionator.blogs.nytimes.com/2008/01/03/outsourced-wombs/?_r=0.
30. Weisberg, D. Kelly, ed. *Applications of Feminist Legal Theory to Women's Lives: Sex, Violence, Work, and Reproduction*. Philadelphia: Temple University Press, 1996.
31. Wikler, Norma J. "Society's Response to the New Reproductive Technologies: The Feminist Perspective." *Southern California Law Review* 59, No.5 (1986): 1043-57.
32. World Health Organization. "Infertility Definitions and Terminology." Accessed 15 September 2016. <http://www.who.int/reproductivehealth/topics/infertility/definitions/en/>.

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Farhat Moazam, "Islamic perspectives on abortion," *Bioethics Links*, vol. 1, no. 2 (2005).
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Islamic Perspectives on Abortion

Farhat Moazam

Islam does not have a central interpretive authority akin to the Catholic Church thus a diversity of opinions can be found on the issue of abortion within historical and contemporary *fatawa* of *fuqaha*. Nevertheless, broad consensus exists in many areas as all jurists rely on the Quran and the *Sunna* as primary sources, and utilize a common methodology to develop arguments.

The Quran and Hadith

Two verses of the Quran refer in detail to the stages of fetal development (22:4 and 23:12-14). Both describe 3 stages in the progressive development of the fetus beginning from a drop or life germ (*nutfah*), progressing to congealed blood or a leech (*'alaqa*), and then to a lump or fetus (*mudgha*). The Quran refers to the creation of 'another creature' (*khalqan akharan*) following the completion of these 3 stages but does not mention the duration of each.

Sahih Bukhari and *Sahih Muslim*, considered to be among the best of the six authentic collections of Hadith, report the Prophet as describing each of the 3 stages lasting for 40 days, and at 120 days of gestation, "an angel is sent to breathe the soul" into the fetus. This point in gestation is unanimously interpreted by Muslim jurists as the time of "ensoulment" of the fetus. This Hadith and the Quranic verses play a central role in juristic interpretations of the permissibility or prohibition of abortion under Islamic Law.

Schools of Jurisprudence (*al-Madhahib al-Fiqhiyya*)

The Quran and Hadith repeatedly affirm the sanctity of life, and there is agreement that aborting a fetus is a reprehensible act. There is a consensus that the fetus is a separate entity from the mother, and juridical rulings reflect that it matures progressively in "personhood" and legal rights from the time of conception to birth. But keeping medical and social realities of the *umma* in mind, jurists have debated exceptional circumstances under which abortion may be considered permissible.

1. Abortion beyond 120 days of gestation (post-ensoulment). The vast majority of jurists from Sunni and Shi'i Schools of Jurisprudence categorically prohibit this practice. Exceptions are allowed in instances when the life of the mother is at stake; this is based on the juristic principles that "the mother is the origin or root, whereas the embryo is a branch," and that "a greater evil (in this case the death of the mother) should be warded off by the lesser evil (the death of her fetus)."

A small minority of jurists allow abortion if in the opinion of "expert" physicians the fetus is severely deformed or not likely to survive following birth.

2. Abortions prior to 120 days of gestation. Considerable differences of opinion can be found both within and between different Schools of Jurisprudence.

* **Hanafi School** (Sunni Muslims worldwide, Turkey, Asian subcontinent including Pakistan): The majority opinion holds that abortion is permissible prior to 120 days if justifiable reasons exist. A small

minority has ruled that abortion is permissible on the demand of husband and wife; a few allow it with the wife's permission alone for valid medical reasons but prefer permission from both spouses.

Valid reasons include ill health of the mother, risks of difficult or obstructed labor, complicated pregnancies in the past requiring another Caesarian section for delivery, and if the woman is still suckling a baby and the father does not have means to procure milk for another offspring. In this case, the survival of the existing child is given precedence over that of the fetus. Abortions to avoid economic hardships are not condoned by most jurists, and abortion as means of birth control is condemned by all.

In the last decade, a few *fatawa* have been given permitting abortion following rape or incest if in the opinion of physicians the pregnancy will result in mental and psychological harm to the mother. It is important to note that Muslim jurists rely on physicians to assess medical indications for aborting a woman.

* **Maliki School** (predominantly Egypt, Spain, Hijaz, Sudan, North and West Africa): The jurists of this School are generally the most conservative and a majority prohibits abortions even in the first 40 days of gestation. This is based on a view that as the destiny of all conceived embryos is ensoulment, the fetus must not be destroyed at any stage.

* **Shafi'i School** (Egypt, Iraq, Syria, East Africa, parts of Sudan, some Asian countries including Malaysia): The jurists are divided in their opinions. Some allow abortion in the *nutfah* and *'alaqa* stages (first 80 days); a few, including Imam al-Ghazali who is liberal in his indications for contraception, prohibit it absolutely.

* **Hanbali School** (Saudi Arabia and scatterings in other Muslim countries): A majority of jurists allow abortion only in the first 40 days; a minority permits it up to 80 days of gestation.

* **Zaydi (Shi'ite) School** (Parts of Yemen and Iran): Jurists generally allow abortion prior to 120 days using in their reasoning an analogy to *al-azal* (coitus interruptus) which is permissible.

* **The Imami or Ja'fari (Shi'ite) School** (Largest Shi'i School with followers in Iran, Iraq, Syria, South Lebanon, Kuwait, Afghanistan, Pakistan and India): Jurists are generally among the most conservative on this issue and a majority of them do not permit abortion at any stage.

Points for Reflection

The variety of legal opinions on abortions, set within a framework of interpretations of Quran and *Sunna*, offer a collage rather than a uniform picture. This diversity of views, extending from the largely permissive stance of the Hanafi School to the relatively restrictive views of the Maliki School, is nevertheless considered in conformity with Islamic Law. It reflects the well known Hadith of the Prophet in which he is reported to have said, "The difference of opinions found within my *umma* is a blessing."

Deliberations about permissibility or prohibition of abortions are not couched in a language of rights of the mother versus the fetus; they center on the potential of harm to the mother, predominantly physical but more recently emotional and psychological, and the consequences of these on the family unit of which she is a component. Expertise of responsible healthcare professionals and their familiarity with the existing realities of the woman and her family, assume a critical role in decision making by contributing the *context* for pragmatic application of *textual* principles provided by Muslim jurists.

Suggested Reading

* Abdel Rahim Omran, *Family Planning in the Legacy of Islam*, (London, New York: Routledge Publishers, 1992). This is a superb, comprehensive collection of opinions and *fatawa* compiled by Dr.

Omran, Chief Advisor to the Al-Azhar International Islamic Center in Cairo and Professor of Healthcare Services at George Washington University.

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Sharmeen Khan, "Legal aspects of abortion: An international overview," *Bioethics Links* vol. 1, no. 2 (2005)

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Legal aspects of abortion: An international overview

Sharmeen Ali Khan

Abortion is defined as terminating pregnancy before the fetus is viable or able to sustain life independently. Abortion was considered illegal almost all over the world till the middle of the last century. However, in recent years in most of the developed world, as in certain developing countries, laws restricting abortion have been relaxed.

In about two thirds of the countries of the world, abortion may now be performed in relatively legitimate circumstances. Presented below is a brief, legal synopsis.

In 1973, the US Supreme Court established the current law on abortion via the *Roe v. Wade* decision. This focused on privacy and the right of a woman to terminate her pregnancy during the first trimester, and her "right to choose." This right may not be forbidden even by an act of Congress.

In UK until 1938, abortion was prohibited. However, after the famous *Bourne* case, whereby Dr. Aleck Bourne was acquitted after performing an illegal abortion on a rape victim, it became legal to perform abortions on mental health grounds. This case was adopted as a legal precedent in most Commonwealth countries.

Italian law allows women to get an abortion for health, social or financial reasons within the first ninety days of the pregnancy, provided a doctor's certificate is obtained and the woman undergoes counseling. Abortion after 90 days is permitted if continued pregnancy endangers the life or physical or mental health of the woman or if the fetus is deformed.

In Belgium, abortion is legalized since 1990 and the law allows a woman, whose condition is judged by two doctors to be under distress, to obtain an abortion. The term "in distress" may be interpreted to include not just physical, but also mental distress. France also has extremely liberal abortion laws.

China, has the world's most open policy on abortion and abortion is free upon the request of the woman. India, another country grappling with over population, has legalized abortion since 1971.

Islamic Countries:

In Zimbabwe, the Termination of Pregnancy Act of 1977 prohibits abortion except in official cases of rape or incest, fetal anomaly, or when the woman's life is endangered by the pregnancy.

Here is an overview of the legal situation regarding abortion in some of the Islamic countries. In Bangladesh, although abortion is prohibited, doctors perform procedures without a pregnancy test in the name of "menstrual regulations." In this case, since pregnancy is not clinically confirmed, the law is circumvented.

In Indonesia, the penal code prohibits abortion; however, the health law of 1992 leaves the status of abortion in the Indonesian law ambivalent.

Abortion is illegal in Iran except to save the life or physical or mental health of a woman, or in cases of fetal impairment. In Malaysia abortion is allowed if pregnancy poses physical or mental risks to the mother's health. In most of the Arab world, abortion is prohibited unless the mother's life is in danger and in some cases only with the express permission of the father.

The Pakistan Penal Code (PPC):

For the purpose of criminalizing abortion the PPC utilizes two stages of pregnancy:

Section 338 of the Pakistan Penal code provides that "Whoever causes a woman with child whose organs have not been formed, to miscarry, if such miscarriage is not caused in good faith for the purpose of saving the life of the woman or providing necessary treatment to her, is said to cause *Isqat-i-Haml*. The punishment is provided by section 338 which states that anyone who causes the *Isqat-Haml* is liable to a punishment of three years if the abortion is performed by the woman's consent, otherwise a maximum of ten years."

Abortion in the earlier stage of pregnancy is not a crime if carried out to provide necessary treatment. However, the term "necessary treatment" is not defined and open to interpretation.

Section 338 B and C of the Pakistan Penal Code provide that termination of a child whose limbs have been formed for any other reason than to save the life of the mother shall be liable to pay *Diyat* (blood money) and such person is also liable to be punished for up to seven years imprisonment.

In view of the provision stated above, abortion is only permitted to save life of the mother after the first trimester. To that extent the law is in line with the majority of the countries in the world which restrict abortion to the first trimester.

From the above it is clear that at present almost two-thirds of the world's women reside in countries where abortion may be obtained on request or for a broad range of social, economic or personal reasons. However, the majority of women who seek abortion still get it in the most covert circumstances.

Useful Links

- Claude Sureau, "From transgression to pragmatism in reproductive medicine," *Reproduction Nutrition Development*, vol. 45, no. 3 (2005): 307-319.
- Adamson S. Muula, "Ethical and practical consideration of women choosing cesarean section deliveries without "medical indication" in developing countries," *Croatian Medical Journal*, vol. 48, no.1 (2007): 94.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2080500/pdf/CroatMedJ_48_0094.pdf.
- Kamyar M. Hedayat, P. Shooshtarizadeh, M. Raza, "Therapeutic abortion in Islam: contemporary views of Muslim Shiite scholars and effect of recent Iranian legislation," *Journal of Medical Ethics*, vol. 32, no. 11 (2006): 652-657.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563289/pdf/652.pdf>.
- Tuba Hassan, "Would surrogacy ever be accepted in Pakistan?" *The Express Tribune*, (2014).
<http://blogs.tribune.com.pk/story/24786/would-surrogacy-ever-be-accepted-in-pakistan/>.

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Clinical Ethics

2.7: HIV and Sexually Transmitted Diseases

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Case for Discussion

You have a well established general practice in a middle class neighborhood of Karachi. One of your patients, 25 year old Mr. Ahmed whom you have known for several years confides in you that he has spent about six months abroad during which time he has had unprotected sexual encounters with multiple paid partners. He has a morbid fear of having contracted AIDS, and wants you to test him for it, in absolute secrecy.

You send out the HIV test in accordance with his wishes. The report comes back as positive for HIV. Ahmed is obviously devastated. He implores you not to tell anyone of his condition. You reassure him and arrange an appointment with an appropriate specialist.

Saamia is a 22 year old girl whose family has been your patient for several years as well. Saamia's father arrives in the clinic for routine hypertension follow up and informs you that she is engaged to be married to Ahmed. As you know both the boy and the girl since they were young children, he says it is important that you come to the wedding.

What are the ethical issues you are faced with?

What will you do, and why?

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www.who.int/hiv/pub/vct/statement/en/WHO, (2004):1-3
Open source document.



UNAIDS/WHO Policy Statement on HIV Testing

The Context

As access to antiretroviral treatment is scaled up in low and middle income countries, there is a critical opportunity to simultaneously expand access to HIV prevention, which continues to be the mainstay of the response to the HIV epidemic. Without effective HIV prevention, there will be an ever increasing number of people who will require HIV treatment. Among the interventions which play a pivotal role both in treatment and in prevention, HIV testing and counselling stands out as paramount.

The current reach of HIV testing services remains poor: in low and middle income countries only 10 per cent of those who need voluntary counselling and testing, because they may have been exposed to HIV infection, have access to it. Even in settings in which voluntary counselling and testing is routinely offered, such as programmes for prevention of mother-to-child transmission, the number of people who avail themselves of these services remains low in many countries. The reality is that stigma and discrimination continue to stop people from having an HIV test.

To address this, the cornerstones of HIV testing scale-up must include improved protection from stigma and discrimination as well as assured access to integrated prevention, treatment and care services. The conditions under which people undergo HIV testing must be anchored in a human rights approach which protects their human rights and pays due respect to ethical principles. (cf Appendix 1). Young people require special attention to their needs through the provision of confidential youth friendly health services. Public health strategies and human rights promotion are mutually reinforcing.

The conditions of the '3 Cs', advocated since the HIV test became available in 1985, continue to be underpinning principles for the conduct of HIV testing of individuals. Such testing of individuals must be:

- **confidential**
- be accompanied by **counseling**
- only be conducted with informed **consent**, meaning that it is both informed and voluntary.

In many low and middle income countries, the primary model for HIV testing has been the provision of **client-initiated** voluntary counseling and testing services. Increasingly, **provider-initiated** approaches in clinical settings are being promoted, i.e. health care providers routinely initiating an offer of HIV testing

in a context in which the provision of, or referral to, effective prevention and treatment services is assured. To reach people in need of treatment, tens of millions of tests will have to be conducted among those who may have been exposed to HIV.

UNAIDS/WHO recommend that the following four types of HIV testing be clearly distinguished:

1) Voluntary Counselling and Testing

Client-initiated HIV testing to learn HIV status provided through voluntary counselling and testing, remains critical to the effectiveness of HIV prevention. UNAIDS/WHO promote the effective promotion of knowledge of HIV status among any population that may have been exposed to HIV through any mode of transmission. Pre-testing counselling may be provided either on an individual basis or in group settings with individual follow-up. UNAIDS/WHO encourage the use of rapid tests so that results are provided in a timely fashion and can be followed up immediately with a first post-test counselling session for both HIV-negative and HIV- positive individuals.

2) Diagnostic HIV Testing is Indicated

Whenever a person shows **signs or symptoms** that are consistent with HIV-related disease or AIDS to aid clinical diagnosis and management. This includes HIV testing for all **tuberculosis** patients as part of their routine management.

3) A Routine Offer of HIV Testing by Health Care Providers should be made to All Patients Being:

- assessed in a sexually transmitted infection clinic or elsewhere for a sexually transmitted infection - to facilitate tailored counselling based on knowledge of HIV status
- seen in the context of pregnancy - to facilitate an offer of **antiretroviral prevention of mother-to-child transmission**
- seen in clinical and community based health service settings where **HIV is prevalent and antiretroviral treatment is available** (injecting drug use treatment services, hospital emergencies, internal medicine hospital wards, consultations etc.) but who are **asymptomatic**.

Explicit mechanisms are necessary in provider-initiated HIV testing to promote **referral to post-test counselling services** emphasising prevention, for all those being tested, and to **medical and psychosocial support**, for those testing positive. The basic conditions of confidentiality, consent and counselling apply but the standard pre-test counselling used in VCT services is adapted to simply ensure informed consent, without a full education and counselling session. The minimum amount of information that patients require in order to be able to provide informed consent is the following:

- the clinical benefit and the prevention benefits of testing
- the right to refuse
- the follow-up services that will be offered and
- in the event of a positive test result, the importance of anticipating the need to inform anyone at ongoing risk who would otherwise not suspect they were being exposed to HIV infection

For provider-initiated testing, whether for purposes of diagnosis, offer of antiretroviral prevention of mother-to-child transmission or encouragement to learn HIV status, patients retain the right to refuse testing, i.e. to 'opt out' of a systematic offer of testing.¹

4) Mandatory HIV Screening

UNAIDS/WHO support mandatory screening for HIV and other blood borne viruses of all blood that is destined for transfusion or for manufacture of blood products. Mandatory screening of donors is required

prior to all procedures involving transfer of bodily fluids or body parts, such as artificial insemination, corneal grafts and organ transplant.

UNAIDS/WHO do not support mandatory testing of individuals on public health grounds. Voluntary testing is more likely to result in behaviour change to avoid transmitting HIV to other individuals. Recognising that many countries require HIV testing for immigration purposes on a mandatory basis and that some countries conduct mandatory testing for pre-recruitment and periodic medical assessment of military personnel for the purposes of establishing fitness, UNAIDS/WHO recommend that such testing be conducted only when accompanied by counselling for both HIV-positive and HIV-negative individuals and referral to medical and psychosocial services for those who receive a positive test result.

¹HIV testing without consent may be justified in the rare circumstance in which a patient is unconscious, his or her parent or guardian is absent, and knowledge of HIV status is necessary for purposes of optimal treatment.

Appendix 1 Ensuring a Rights Based Approach

The global scaling up of the response to AIDS, particularly in relation to HIV testing as a prerequisite to expanded access to treatment, must be grounded in sound public health practice and also respect, protection, and fulfillment of human rights norms and standards.

The voluntariness of testing must remain at the heart of all HIV policies and programmes, both to comply with human rights principles and to ensure sustained public health benefits.

The following key factors, which are mutually reinforcing, should be addressed simultaneously:

1. Ensuring an ethical process for conducting the testing, including defining the purpose of the test and benefits to the individuals being tested; and assurances of linkages between the site where the test is conducted and relevant treatment, care and other services, in an environment that guarantees confidentiality of all medical information;
2. Addressing the implications of a positive test result, including non-discrimination and access to sustainable treatment and care for people who test positive;
3. Reducing HIV/AIDS-related stigma and discrimination at all levels, notably within health care settings;
4. Ensuring a supportive legal and policy framework within which the response is scaled up, including safeguarding the human rights of people seeking services;
5. Ensuring that the healthcare infrastructure is adequate to address the above issues and that there are sufficient trained staff in the face of increased demand for testing, treatment, and related services.

UNAIDS Global Reference Group on HIV/AIDS and Human Rights

Useful Links

- “HIV Disclosure and the Law: A Resource Kit for Service Providers,” *Canadian HIV/AIDS Legal Network* (2012): 1-6. <http://www.aidslaw.ca/site/wp-content/uploads/2014/02/Chapter1-ENG.pdf>.
- Michael D. Stein, Kenneth A. Freedberg, Lisa M. Sullivan, et al., "Sexual ethics: disclosure of HIV-positive status to partners," *Archives of Internal Medicine*, vol. 158, no. 3 (1998): 253-257. https://www.researchgate.net/journal/0003-9926_Archives_of_Internal_Medicine.
- Michael Parsa, Matthew J. Walsh, "Ethics seminars HIV testing, consent, and physician responsibilities," *Academic Emergency Medicine*, vol. 8, no. 12 (2001): 1197- 99.
- Morris Gallagher, “AIDS and HIV infection: Ethical problems for General Practitioners,” *Journal of the Royal College of General Practitioners*, vol. 38 (1988) 414-417. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1711603/pdf/jroyalcgprac00021-0027.pdf>.
- Peter F. Omonzejele, “Some Ethical Issues in HIV/AIDS care,” *African Journal of Reproductive Health* (Special Edition), vol. 18, no. 3 (2014): 14-16. <http://www.bioline.org.br/pdf?rh14056>.
- “Sexually transmitted disease: A private matter?” *American Family Physician*, vol. 66, no. 7 (2002):1351-1356. <http://www.aafp.org/afp/2002/1001/p1351.html>.
- Kilian P Dunphy, “Consent, confidentiality and curing sexually transmitted infection: an ethical trilemma,” *SAGE Journals*, vol. 22, no. 5 (2011). <http://journals.sagepub.com/doi/pdf/10.1258/ijsa.2009.009373>.

Clinical Ethics

2.8: Resource Allocation

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The Ethics and Reality of Rationing in Medicine

Leslie P. Scheunemann, Douglas B. White

Rationing is the allocation of scarce resources, which in health care necessarily entails withholding potentially beneficial treatments from some individuals. Rationing is unavoidable because need is limitless and resources are not. How rationing occurs is important because it not only affects individual lives but also expresses society's most important values. This article discusses the following topics: (1) the inevitability of rationing of social goods, including medical care; (2) types of rationing; (3) ethical principles and procedures for fair allocation; and (4) whether rationing ICU care to those near the end of life would result in substantial cost savings.

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Abbreviations: QALY = quality-adjusted life year; UNOS = United Network for Organ Sharing

Editor's note

This review addresses the 15th topic in the core curriculum of the ongoing "Medical Ethics" series. To view all articles included in the "Medical Ethics" series, visit <http://chestjournal.chestpubs.org/cgi/collection/medethics>. —Constantine A. Manthous, MD, FCCP, Section Editor, Medical Ethics

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Health-care reform has remained a controversial sociopolitical issue for the last 2 decades. Part of the controversy at the policy level arises from the question of whether health-care reform will involve

rationing medical care. This topic raises fears about unfair treatment of individuals,¹ which have been inflamed by assertions that rationing devalues human life.² Physicians have struggled with the controversy surrounding rationing.^{3,4} Some deny that rationing occurs and contend that their professional obligations require them not to participate in rationing.⁵⁻⁷ Others admit to rationing^{8,9} and see just allocation of medical care as part of physicians' ethical duties.¹⁰ Intensivists share this ambivalence. In a recent survey, only 60% vouched that they provide "every patient all beneficial therapies without regard to costs."¹¹ To be thoughtful participants in the social debate about rationing in medicine, physicians must be well informed. The purpose of this article is to address the following topics:

- (1) the inevitability of rationing of social goods, including medical care;
- (2) types of rationing;
- (3) ethical principles and procedures for fair allocation; and
- (4) whether rationing ICU care to those near the end of life would result in substantial cost savings.

What Is Rationing?

Although rationing has been defined in slightly different ways by different groups, most definitions cluster around one central idea: denying a potentially beneficial treatment to a patient on the grounds of scarcity.¹² The focus on potentially beneficial treatments is appropriate because virtually no treatment in medicine offers certain benefit for an individual patient and because a central point of controversy is whether the potential benefit is large enough or likely enough to occur in order to justify the expense. In this document, we use the terms "rationing" and "resource allocation" synonymously, although we acknowledge that the emotional valence of the two terms is clearly different. It is also important to note that not all efforts to control health-care costs involve rationing. For example, choosing a less expensive treatment over a more expensive one does not entail rationing if both are equally effective, because selecting the less costly of the two does not result in the patient being denied a potentially beneficial treatment.¹² In addition, strategies focused on reducing administrative costs and waste in health care (e.g., reducing duplicative testing and administrative inefficiencies) are generally not rationing because they do not entail denying patients potentially beneficial care.

Rationing Is Unavoidable

In many industrialized countries, social goods including health care, education, defense, infrastructure, environmental protection, and public health draw funding from a common pool. Although need for such social goods is limitless, the resources available to supply them are limited.^{6,13-15} Inevitably, difficult choices must be made to allocate finite resources in a way that achieves a reasonable balance across the range of important social goods. Attempting to meet all health-care needs would likely overwhelm our capacity to supply basic elements of other social goods, such as public safety, education, and defense. Therefore, some degree of rationing of health care is necessary for the overall well-being of society.

Rationing decisions pervade daily practice in ICUs.^{5,12-16} For example, it is common to transfer a patient out of an ICU when she might still derive some small degree of benefit from ongoing monitoring; such transfers accommodate the needs of sicker patients in the face of a finite number of ICU beds. Physicians in ICUs also routinely ration their time.¹² They must decide which patients to see first and how much time to spend with each. Physicians also must balance the needs of patients against their nonprofessional obligations, such as responsibilities to their families. It is undoubtedly true that physicians cannot provide every potential benefit to every critically ill patient. Therefore, the reality of practice in ICUs is that patients are routinely denied some potential benefit however small through implicit rationing decisions made by physicians at the bedside.

The Appropriateness of Rationing Is Context Specific

The necessity of some rationing in medicine does not mean that all such rationing is ethically justifiable, and a justifiable rationing decision in one health-care system may not be similarly justifiable in another.

One example is the rules in many health systems requiring less expensive, less beneficial drugs to be first-line choices over more expensive, more beneficial drugs. This type of rationing is relatively easy to justify in single-payer systems (e.g., the government-sponsored health-care plans in Canada and many European countries), in which savings are reinvested in programs to improve the health of the population. Such rationing decisions are harder to justify in a for-profit health system with wasteful administrative mechanisms and in which most profits are passed on to employees and shareholders rather than invested in improving the quality of care for patients.

Levels and Transparency of Rationing

Rationing can occur at multiple levels. The clearest conceptual distinction exists between “macroallocation” and “microallocation” decisions.^{17,18} Macroallocation occurs at the societal level and includes decisions about how to allocate funds across a range of public goods. For example, macroallocation decisions determine how a particular society’s public funds are allocated across social goods, such as defense, education, infrastructure, public health, and health care. Microallocation decisions involve bedside decisions about whether an individual patient will or will not receive a scarce medical resource. Although conceptually distinct, macroallocation decisions and microallocation decisions are related. For example, restrictive macroallocation decisions regarding health-care funding will create more situations in which individual patients must be denied potentially beneficial treatments.

Perhaps the most straightforward examples of the rationing in medicine occur when there is an absolute scarcity of a medical resource, such as organs for transplantation. The United Network for Organ Sharing (UNOS) has developed policies to ration according to weighted organ-specific criteria, such as time on the waiting list, severity of illness, human leukocyte antigen matching, prognostic information, and other considerations.¹⁹⁻²² These policies are examples of rationing at the micro level. UNOS explicitly acknowledges that many will die without receiving an organ because of the need to ration. Conceivably, more funding of initiatives to encourage organ donation at the macro level would decrease deaths of patients on transplant waiting lists but would likely come at the cost of funding other important social programs. Scarcity is unavoidable in the realm of social goods, and the need to ration is one consequence.

Rationing also occurs because of general fiscal scarcity rather than an absolute scarcity of a particular medical resource. For example, in the early 1990s, Oregon had to cope with escalating medical expenditures for Medicaid recipients in the face of budget deficits. The resulting Oregon Health Plan concurrently set a firm annual health-care budget and expanded the Medicaid eligibility criteria to include all below the federal poverty level.^{23,24} The initial macroallocation decision balanced state health-care spending against competing social goods, such as education, infrastructure, and prisons.²⁴ The second macroallocation traded providing a larger range of health-care services to less than one-half the state’s poor for providing a basic level of health care to all Oregonians living in poverty.^{23,25,26} Oregon covered services according to a published priority list until projected expenditures exhausted the budget; there was not publicly funded coverage for the remaining services.²³⁻²⁶ This entailed denying beneficial therapies to some patients (microallocation).

Both the UNOS strategy for organ allocation and the Oregon Health Plan are examples of explicit rationing; these rationing decisions arise from stated principles and rules. In contrast, implicit rationing occurs without formally stated rules or principles. The 46 million uninsured in the United States are an example of implicit rationing at the macro level.^{27, 28} Intensivists’ decisions about how much time to spend with each patient are also examples of implicit rationing because they are generally not based on publicly disclosed reasons. In general, implicit rationing raises more concerns about fairness than explicit rationing because the basis of the decisions is not disclosed and because unspoken and illegitimate biases may exert undue influence on the decisions.

Empiric Data on Rationing in ICU's

Empiric data from multiple countries document the rationing of medical services in ICUs. In 10,000 ICU bed triage decisions across North America, Europe, Israel, and Hong Kong, at least 15% of patients were refused ICU admission, of which approximately 15% were attributed to lack of beds.^{9,29,30} Additionally, during times of ICU bed shortages, admitted patients were more ill at both ICU admission and discharge, average lengths of stay were shorter, and fewer patients were admitted for monitoring, which suggests that some patients are denied potentially beneficial treatment in times of ICU bed shortages.⁹ Some centers have attempted to reduce ICU use by making mechanical ventilation available on the wards. This also constitutes rationing because ICU care is associated with lower rates of adverse events and mortality compared with providing mechanical ventilation outside ICUs.^{31,32}

A survey of US intensivists suggests that many believe that they do not ration.¹¹ These results may reflect a lack of understanding of what rationing is or may reflect a symbolic belief about what physicians should do. In either case, the lack of insight about the inevitability of rationing in ICUs is problematic, because it suggests that many intensivists are not well positioned to be informed participants in the social conversation about how best to make the difficult decisions regarding competing social goods.

What Principles Could Guide Rationing

A substantial barrier to moving from implicit to explicit approaches to rationing health care is the failure to specify what principle(s) should guide allocation. Many principles could form the basis of rationing decisions in health care, each of which represents a different interpretation of distributive justice. For example, the following have been proposed as valid material principles of distributive justice: (1) to each person an equal share, (2) to each according to need, (3) to each according to effort, (4) to each according to free market conditions, (5) to each so as to maximize overall usefulness.²² A more comprehensive description of the principles and how they might be combined into multiprinciple allocation strategies—can be found elsewhere.^{22,33,34}

A foundational debate about distributive justice is how to navigate the conflicting impulses to maximize efficiency (making decisions so as to produce the most good with the least expenditure), equity (treating individuals equally), and prioritarian conceptions of justice (favoring the worst off). Therefore, we briefly discuss three approaches to allocating scarce resources grounded in these radically different philosophical notions of justice: utilitarianism, egalitarianism, and prioritarianism. We also introduce the “rule of rescue.”

To Each to Maximize Overall Quality-Adjusted Life Years: Utilitarianism

In general terms, utilitarianism seeks to maximize overall benefits at the societal level. There are numerous approaches to quantifying benefits related to health care. Many health economists advocate use of the quality-adjusted life years (QALYs) as the best metric.³⁵ Rationing by QALYs involves two steps: selecting outcome measures that adjust life-years for quality, and then allocating so as to maximize QALYs. Use of QALYs allows comparisons regarding effectiveness across diseases and services that would otherwise be difficult to compare.³⁵ For example, ICU treatment of life-threatening drug intoxication costs approximately \$620 per QALY, ICU treatment of acute renal failure costs approximately \$30,625 per QALY, and drotrecogin α treatment of patients with systemic inflammatory response syndrome and APACHE (Acute Physiology and Chronic Health Evaluation) II scores 25 costs \$400,000 per QALY.^{36, 38}

Rationing by maximizing QALYs has limitations. First, there are important unanswered questions regarding the best methods to quantify quality of life.^{23,33} For example, a person who has over time adapted to using a wheelchair may rate her quality of life the same as someone who is ambulatory, whereas someone recently confined to a wheelchair might rate her quality of life lower. These differences

would lead to substantially different cost per QALY calculations depending on the time point at which quality-of-life assessments were obtained.

Additionally, simple strategies to maximize QALYs fail to consider how the benefits are distributed. For example, saving 95 QALYs distributed among two people in a population of 10 with the disease is not necessarily superior to saving 94 QALYs that are equally distributed across all 10 patients (9.4 QALYs per patient),^{33,39} because of egalitarian concerns about equal distribution of benefits among similarly situated patients. Discounting lower quality of life may also systematically disadvantage those with chronic illness compared with those with good health; such practice opposes a commonly held moral intuition that it is important to help the worst off, or at least not to enable their poor health to be a self-fulfilling prophecy.

Despite these limitations, the National Institute for Health and Clinical Excellence in the United Kingdom uses QALYs to guide coverage decisions.⁴⁰ For example, drug treatments costing £20,000-30,000 per QALY are not considered cost-effective and often are not approved for funding. In the United States, public mistrust of policies incorporating cost considerations has made the use of QALYs and cost-effectiveness analysis a political quagmire.^{35, 41}

To Each an Equal Opportunity: Egalitarianism

Egalitarianism emphasizes the equal moral status of individuals by trying to provide equal opportunity to have the basic goods in life.²² A straightforward example of an egalitarian approach to rationing is a lottery to determine priority for receiving a scarce resource.^{18,33} Many citizens have strong moral intuitions toward egalitarian allocation strategies, even when they come at the expense of utility maximization.⁴² For example, if there were an insufficient supply of ICU beds for the number of patients in need, an egalitarian might advocate for a lottery to randomly select which patients would be admitted. Lotteries require little knowledge about recipients, can occur rapidly, and resist corruption.³³ On the other hand, lotteries and egalitarian principles of justice in general are insensitive to factors that are also intuitively important to many, such as patients' need and likelihood of deriving benefit from treatment.³³

First-come, first-served strategies to allocate scarce resources appear to be egalitarian, but often are not.^{18,33} Existing guidelines support allocating ICU beds in this way,^{43,44} and prior to 2005 waiting time was the primary criterion for allocating lungs for transplantation.¹⁹ However, time on the wait list for organ transplantation is not "random" in two ways. First, it favors those with diseases who are well enough to wait the longest.¹⁹ Second, those with power, knowledge, and connections often have the social resources to more quickly secure a position in the queue compared with those who have poor health-care access.^{18, 33}

To Each to Favor the Worst Off: Prioritarianism

In general terms, prioritarianism attempts to help those who are considered the worst off by giving them priority in situations in which all cannot receive a particular resource.³³ For example, a prioritarian might preferentially allocate medical resources to the young over the old because the young have had the least chance to live through life's stages.^{33,34} This "life cycle principle" which is one example of a prioritarian allocation strategy has been advocated as a way to allocate scarce organs for transplantation and mechanical ventilators during an influenza pandemic.^{34,45} The justification for this principle does not rely on considerations of one's intrinsic worth or social usefulness. Rather, the goal is to give all individuals equal opportunity to live a normal life span. When used alone to guide allocation decisions, the life cycle principle ignores prognostic differences among individuals. This type of objection points to the possibility that multiprinciple allocation strategies may better account for the complex moral considerations at play in such decisions compared with single-principle allocation strategies.³⁴

The Rule of Rescue

The rule of rescue describes a powerful psychologic impulse to attempt to save those facing death, no matter how expensive or how small the chance of benefit. The philosopher Albert Jonsen coined the term and describes it as “the moral response to the imminence of death [which] demands that we rescue the doomed.”⁴⁶ In many ways, the impulse underlying the rule of rescue is an admirable human response to suffering. However, it also can lead to decisions that confound priority setting meant to maximize population-level outcomes. When Oregon refused to cover a potentially lifesaving bone marrow transplantation for 7-year-old Coby Howard, there was tremendous public outrage and negative media coverage, which likely arose as a consequence of not satisfying the psychologic impulse to rescue identifiable persons facing death.⁴⁷ The emotional costs of rationing ICU care would likely be similarly high because it would lead to the loss of identifiable lives.

Conflicts between Efficiency, Equity, and the Rule of Rescue

The deep moral tensions between efficiency, equity, and responding to those facing death should not be underestimated. In surveys of physicians, citizens, and economists about how to balance such trade-offs, people generally prioritize treatment that can be made available to everyone, but this view is tempered by impulses to maximize usefulness^{34,45,46} and to rescue those in need.^{42,48-52} Finding an acceptable balance between these competing ethical goals remains a serious challenge for the development of explicit rationing policies.

Fair Processes of Rationing

In morally pluralistic societies, reasonable people may be unable to agree about which principles should guide rationing. When such conflicts arise concerning high-stakes outcomes, using fair processes to make decisions acquires special ethical importance.^{14,53} Daniels and Sabin¹⁴ and Daniels⁵³ have proposed four characteristics of fair processes related to allocation: oversight by a legitimate institution, transparent decision making, reasoning according to information and principles that all can accept as relevant, and procedures for appealing and revising individual decisions.^{14,53} A fifth aspect of procedural fairness is meaningful public engagement.⁵⁴ This step is important to identify unanticipated needs and values and to obtain public support.^{54,55}

The approach used to develop the Oregon Health Plan priority lists had many elements of procedural fairness: The process was under the authority of the state government, which is a legitimate authority for such policies; there was extensive public engagement; priority setting was explicit and incorporated expert opinion; and mechanisms were created for review and refinement of the priority list.⁵⁶

Recent work by Baum and colleagues⁵⁴ and Danis and colleagues⁵⁵ has demonstrated the feasibility of public engagement related to priority setting in health care. For example, focus groups with citizens about priority setting during a severe influenza outbreak revealed a strong sense of support for interventions focused on the well-being of the community at large. Citizens also raised other ethical, economic, religious, and social concerns that policy makers must consider to develop just policies that will garner compliance.⁵⁵ Other research has focused on engaging community participants in setting priorities for health insurance plans.⁵⁴ Similar exercises have been used for research and policy settings in nine states. Their use improved understanding of the need to limit benefits in order to limit health-care spending, increased community mindedness of group decisions, and allowed groups to set priorities that at least 85% of participants were willing to abide by.

Will Fair Processes Fail for Tragic Choices?

Although public engagement and transparency seem indispensable for ethical priority setting in medicine, critics have argued that the emotionally and morally difficult choices raised by the rationing of life-saving medical therapies may prove resistant to rational debate. In their book *Tragic Choices*, Calabresi and

Bobbitt¹⁸ argue that society is unlikely to be able to produce a durable, acceptable solution to the issue of scarcity in medicine because the consequences of denying these treatments to individual patients are intolerable.

They argue that individuals collectively attempt to deny moral responsibility for their role in choices—no matter how ethical or necessary - that consign individuals to death. This denial involves creating the illusion that the suffering arises out of nature rather than from conscious choices. For example, the safety standards in the mining industry do not create the safest possible environment for coal miners; doing so would be prohibitively expensive and threaten the market competitiveness of mining companies. However, when there is a mine accident and identifiable miners are trapped, nothing is spared to save them. This response supports the illusion that the mining accident was not preventable and that all was done to safeguard the lives at stake, while ignoring the initial decision that allowed people to work in conditions with a certain level of risk.

Two repeating processes characterize tragic choices. First, society iteratively remakes macro- and micro-allocation decisions to make human suffering appear as infrequent and random as possible. Second, society chooses ostensibly noncontroversial values to justify rationing decisions until the inherent conflict with basic values is exposed. For example, when hemodialysis was first developed as a life-saving therapy for patients with renal failure, demand outstripped supply, and the Seattle Dialysis Committee was formed to determine who would receive dialysis.⁵⁷ This panel made decisions that entailed refusing treatment to patients who died as a result. An exposé of the committee's decisions was published in *LIFE* magazine,⁵⁸ which generated a national public firestorm. The public's distaste for allowing identifiable patients to die partly led Congress to authorize universal coverage for hemodialysis. In doing so, society was able to better tolerate the (still unresolved) societal question of how to allocate scarce medical resources because the proposed solution minimized the number of identifiable lives lost. In the last decade, the debate has reemerged in a predictable way, now focused on controlling spending while ensuring a minimum acceptable level of basic care for all. It is not yet clear whether the next iteration of health care reform will produce substantive changes rather than changes that appease our consciences but leave unaddressed the inevitability of tragic choices.

Would Rationing ICU Care Near The End of Life Save Money?

ICU care is expensive and not always successful. In the United States, upward of 0.66% of the gross domestic product is spent on critical care services, and care for those who die in ICUs totals tens of billions of dollars a year.^{16,59,60} It would seem then that the ICU might be an ideal location for rationing. In our experience, some physicians believe that health-care costs should be substantially reduced by strategies that allow unilateral withdrawal of life support in ICUs when patients do not respond fully to a trial of intensive care. However, Luce and Rubenfeld's⁵⁹ analysis of ICU cost structures reveals that the truth is less straightforward. Because 80% of hospitals' budgets are independent of the volume of patients treated (ie, fixed mortgage, maintenance, utilities, and essential personnel salaries), only 20% of costs are modifiable on a per-patient basis (ie, variable medications, diagnostic and therapeutic equipment, or patient care supplies). The analysis suggests that authorizing unilateral withdrawal of life support when ICU care appears to be failing is unlikely to meaningfully reduce costs. Several empiric studies support this claim.^{61,62} Limiting the number of ICU beds built and closing existing ICU beds presents much greater opportunities for cost savings because both fixed and variable costs would be reduced.

Nonetheless, it is certainly true that some cost savings could result from rationing ICU care for patients with relatively poor chances of benefit, especially if rules were developed that delineated situations in which palliative care rather than ICU care would be provided. However, these types of policies would likely be socially divisive and politically challenging, because they would violate the rule of rescue and result in the deaths of identifiable patients.⁶³ Because the modest savings achieved may be outweighed by

the psychologic costs and social outrage, efforts to explicitly ration health care should likely begin with less controversial medical decisions.

Conclusions

Rationing of health care is necessary, unavoidable, and ethically complex. The levels at which health care is rationed, and the transparency of rationing, are important structural considerations in creating a sustainable and just health-care system. Ethical rationing requires deliberate choices guided by reasonably applied principles and fair procedures. How rationing occurs is important because it not only affects individual lives but also expresses what values are most important to society. We live in a world in which need is boundless but resources are not and medicine is not immune to the consequences of this reality.

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Abbreviations

QALY quality-adjusted life year

UNOS United Network for Organ Sharing

Footnotes

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—Constantine A. Manthous, MD, FCCP, Section Editor, Medical Ethics

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References

1. Holtz-Eakin D. All's not fair in health reform bills. *The Boston Globe*. December 10, 2009. http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2009/12/10/all_s_not_fair_in_health_reform_bills. Accessed December 28, 2010.
2. Singer P. Why we must ration healthcare. *The New York Times*. July 15, 2009. www.nytimes.com/2009/07/19/magazine/19healthcare-t.html. Accessed December 28, 2010.
3. Levinsky NG. The doctor's master. *N Engl J Med*. 1984 ; 311 (24): 1573 - 1575 .
4. Strech D, Persad G, Marckmann G, Danis M . Are physicians willing to ration health care? Conflicting findings in a systematic review of survey research. *Health Policy*. 2009 ; 90 (2-3): 113 - 124.
5. Strech D, Synofzik M, Marckmann G. How physicians allocate scarce resources at the bedside: a systematic review of qualitative studies. *J Med Philos*. 2008; 33 (1): 80 - 99.
6. Sulmasy DP. Physicians, cost control, and ethics. *Ann Intern Med*. 1992; 116 (11): 920 - 926.
7. Angell M. The doctor as double agent. *Kennedy Inst Ethics J*. 1993; 3(3): 279 - 286.

8. Hurst SA, Slowther AM, Forde R, et al. Prevalence and determinants of physician bedside rationing: data from Europe. *J Gen Intern Med.* 2006; 21 (11): 1138 - 1143.
9. Sinuff T, Kahn moui K, Cook DJ, Luce JM, Levy MM; Values Ethics and Rationing in Critical Care Task Force Rationing critical care beds: a systematic review. *Crit Care Med.* 2004; 32 (7): 1588 - 1597.
10. Cooke M. Cost consciousness in patient care—what is medical education’s responsibility? *N Engl J Med.* 2010; 362 (14): 1253 - 1255.
11. Ward NS, Teno JM, Curtis JR, Rubenfeld GD, Levy MM. Perceptions of cost constraints, resource limitations, and rationing in United States intensive care units: results of a national survey. *Crit Care Med.* 2008; 36 (2): 471 - 476.
12. Truog RD, Brock DW, Cook DJ, et al; for the Task Force on Values, Ethics, and Rationing in Critical Care (VERICC). Rationing in the intensive care unit. *Crit Care Med.* 2006; 34 (4): 958 - 963.
13. Veatch RM. Physicians and cost containment: the ethical conflict. *Jurimetrics.* 1990; 30 (4): 461 - 482.
14. Daniels N, Sabin J. Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philos Public Aff.* 1997; 26 (4): 303 - 350.
15. King D, Maynard A. Public opinion and rationing in the United Kingdom. *Health Policy.* 1999; 50 (1-2): 39 - 53.
16. Halpern NA. Can the costs of critical care be controlled? *Curr Opin Crit Care.* 2009; 15 (6): 591 - 596.
17. Skowronski GA. Bed rationing and allocation in the intensive care unit. *Curr Opin Crit Care.* 2001; 7 (6): 480 - 484.
18. Calabresi G, Bobbitt P. *Tragic Choices: The Conflicts Society Confronts in the Allocation of Tragically Scarce Resources.* New York, NY: W. W. Norton & Company; 1978.
19. Egan TM, Kotloff RM. Pro/Con debate: lung allocation should be based on medical urgency and transplant survival and not on waiting time. *Chest.* 2005; 128 (1): 407 - 415.
20. Freeman RB Jr, Wiesner RH, Harper A, et al ; UNOS/OPTN Liver Disease Severity Score, UNOS/OPTN Liver and Intestine, and UNOS/OPTN Pediatric Transplantation Committees. The new liver allocation system: moving toward evidence-based transplantation policy. *Liver Transpl.* 2002; 8 (9): 851 - 858.
21. Renlund DG, Taylor DO, Kfoury AG, Shaddy RS; United Network for Organ Sharing. New UNOS rules: historical background and implications for transplantation management. *J Heart Lung Transpl.* 1999; 18 (11): 1065 - 1070.
22. Childress J, Beauchamp T. *Principles of Biomedical Ethics.* New York, NY: Oxford University Press; 2009.
23. Hadorn D. The Oregon priority-setting exercise: quality of life and public policy. *Hastings Cent Rep.* 1991; 21 (3): 11-16.
24. Kitzhaber J, Gibson M. The crisis in health care—The Oregon Health Plan as a strategy for change. *Stanford Law & Policy Review.* 1991; 3 : 64-72.
25. Oberlander J, Marmor T, Jacobs L. Rationing medical care: rhetoric and reality in the Oregon Health Plan. *CMAJ.* 2001; 164 (11): 1583 - 1587.
26. Jacobs L, Marmor T, Oberlander J. The Oregon Health Plan and the political paradox of rationing: what advocates and critics have claimed and what Oregon did. *J Health Polit Policy Law.* 1999; 24 (1): 161 - 180.
27. Feldman R. The cost of rationing medical care by insurance coverage and by waiting. *Health Econ.* 1994; 3 (6): 361 - 372.
28. Kennedy J, Morgan S. Health care access in three nations: Canada, insured America, and uninsured America. *Int J Health Serv.* 2006 ; 36 (4): 697 - 717.
29. Iapichino G, Corbella D, Minelli C, et al. Reasons for refusal of admission to intensive care and impact on mortality. *Intensive Care Med.* 2010; 36 (10): 1772 - 1779.
30. Reignier J, Dumont R, Katsahian S, et al. Patient-related factors and circumstances surrounding decisions to forego life sustaining treatment, including intensive care unit admission refusal. *Crit Care Med.* 2008; 36 (7): 2076 – 2083.
31. Hersch M, Sonnenblick M, Karlic A, Einav S, Sprung CL, Izbicki G. Mechanical ventilation of patients hospitalized in medical wards vs the intensive care unit—an observational, comparative study. *J Crit Care.* 2007; 22 (1): 13 - 17.
32. Lieberman D, Nachshon L, Miloslavsky O, et al. Elderly patients undergoing mechanical ventilation in and out of intensive care units: a comparative, prospective study of 579 ventilations. *Crit Care.* 2010; 14 (2): R48.
33. Persad G, Wertheimer A, Emanuel EJ. Principles for allocation of scarce medical interventions. *Lancet.* 2009; 373 (9661): 423 - 431.
34. White DB, Katz MH, Luce JM, Lo B. Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. *Ann Intern Med.* 2009; 150

- (2): 132 - 138.
35. Neumann PJ, Weinstein MC. Legislating against use of cost-effectiveness information. *N Engl J Med.* 2010; 363 (16): 1495 - 1497.
 36. Woolf SH. Potential health and economic consequences of misplaced priorities. *JAMA.* 2007; 297 (5): 523 - 526.
 37. Sznajder M, Aegerter P, Launois R, Merliere Y, Guidet B, CubRea. A cost-effectiveness analysis of stays in intensive care units. *Intensive Care Med.* 2001; 27 (1): 146 - 153.
 38. Talmor D, Shapiro N, Greenberg D, Stone PW, Neumann PJ. When is critical care medicine cost-effective? A systematic review of the cost-effectiveness literature. *Crit Care Med.* 2006; 34 (11): 2738 - 2747.
 39. Kamm F. *Morality, Mortality: Volume I: Death and Whom to Save from It.* New York, NY: Oxford University Press; 1998.
 40. Measuring effectiveness and cost effectiveness: the QALY. National Institute for Health and Clinical Excellence Website. <http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenesstheqaly.jsp>. Accessed January 25, 2011.
 41. Neumann PJ, Rosen AB, Weinstein MC. Medicare and cost effectiveness analysis. *N Engl J Med.* 2005; 353 (14): 1516 - 1522.
 42. Ubel PA, Baron J, Nash B, Asch DA. Are preferences for equity over efficiency in health care allocation “all or nothing”? *Med Care.* 2000; 38 (4): 366 - 373.
 43. American Thoracic Society. Fair allocation of intensive care unit resources. *Am J Respir Crit Care Med.* 1997; 156 (4 pt 1): 1282 - 1301.
 44. Guidelines for intensive care unit admission, discharge, and triage. Task Force of the American College of Critical Care Medicine, Society of Critical Care Medicine. *Crit Care Med.* 1999; 27 (3): 633 - 638.
 45. Emanuel EJ, Wertheimer A. Public health. Who should get influenza vaccine when not all can? *Science.* 2006; 312 (5775): 854 - 855.
 46. Jonsen AR. Bentham in a box: technology assessment and health care allocation. *Law Med Health Care.* 1986; 14 (3-4): 172 - 174.
 47. Egan T. Rebuffed by Oregon, patients take their life-or-death cases public. *New York Times.* May 1, 1988. <http://www.nytimes.com/1988/05/01/us/rebuffed-by-oregon-patients-take-their-life-or-death-cases-public.html?scp=1&sq=may%201988%20coby%20oregon&st=cse>. Accessed November 6, 2010.
 48. Ubel PA, DeKay ML, Baron J, Asch DA. Cost-effectiveness analysis in a setting of budget constraints—is it equitable? *N Engl J Med.* 1996; 334 (18): 1174 - 1177.
 49. Perneger TV, Martin DP, Bovier PA. Physicians’ attitudes toward health care rationing. *Med Decis Making.* 2002; 22 (1): 65 - 70.
 50. Ubel PA, Loewenstein G, Scanlon D, Kamlet M. Individual utilities are inconsistent with rationing choices: A partial explanation of why Oregon’s cost-effectiveness list failed. *Med Decis Making.* 1996; 16 (2): 108 - 116.
 51. Ubel PA, Loewenstein G. The efficacy and equity of retransplantation: an experimental survey of public attitudes. *Health Policy.* 1995; 34 (2): 145 - 151.
 52. Ubel PA. How stable are people’s preferences for giving priority to severely ill patients? *Soc Sci Med.* 1999; 49 (7): 895 - 903.
 53. Daniels N. Accountability for reasonableness. *BMJ.* 2000; 321 (7272): 1300 - 1301.
 54. Baum NM, Jacobson PD, Goold SD. “Listen to the people”: public deliberation about social distancing measures in a pandemic. *Am J Bioeth.* 2009; 9 (11): 4-14.
 55. Danis M, Ginsburg M, Goold S. Experience in the United States with public deliberation about health insurance benefits using the small group decision exercise, CHAT. *J Ambul Care Manage.* 2010; 33 (3): 205 - 214.
 56. Daniels N. Is the Oregon rationing plan fair? *JAMA.* 1991; 265 (17): 2232 - 2235.
 57. Rescher N. The allocation of exotic medical lifesaving therapy. *Ethics.* 1969; 79 (3): 173 - 186.
 58. Alexander S. They decide who lives, who dies. *LIFE.* November 19, 1962; 53 (19): 102 - 125.
 59. Luce JM, Rubenfeld GD. Can health care costs be reduced by limiting intensive care at the end of life? *Am J Respir Crit Care Med.* 2002; 165 (6): 750 - 754.
 60. Ward NS. Rationing critical care medicine: recent studies and current trends. *Curr Opin Crit Care.* 2005; 11 (6): 629 - 632.
 61. Halevy A, Neal RC, Brody BA. The low frequency of futility in an adult intensive care unit setting. *Arch Intern Med.* 1996; 156 (1): 100 - 104.

62. Sachdeva RC, Jefferson LS, Coss-Bu J, Brody BA. Resource consumption and the extent of futile care among patients in a pediatric intensive care unit setting. *J Pediatr.* 1996; 128 (6): 742 - 747.
63. Newman TB. The power of stories over statistics. *BMJ.* 2003; 327 (7429): 1424 - 1427.

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Ethical Issues in Resource Allocation, Research, and New Product Development

Dan W. Brock, Daniel Wikler

The ethical justification for developing and providing the means to reduce the burden of disease in developing countries is self-evident. Nevertheless, those who pursue these laudable ends encounter ethical dilemmas at every turn. The development of new interventions requires testing with human subjects, an activity fraught with controversy since the dawn of scientific medicine and especially problematic with poor and vulnerable participants in developing countries. Ethical dilemmas arising in setting priorities among interventions and among individuals in need of care are most acute when needs are great and resources few.

We address some of these concerns in this chapter, identifying some of the principal ethical issues that arise in the development and allocation of effective interventions for developing countries and discussing some alternative resolutions. We omit discussion of two other aspects of these ethical decisions: ensuring that the process of decision making is fair and involves the (Daniels 2000; Holm 1998), and respecting legal obligations under international human rights treaties (Gruskin and Tarantola 2001).

Health Resource Allocation

Resource allocation in health and elsewhere should satisfy two main ethical criteria. First, it should be cost-effective limited resources for health should be allocated to maximize the health benefits for the population served. A cost-effectiveness analysis (CEA) of alternative health interventions measures their respective costs and benefits to determine their relative efficiency in the production of health. Costs are measured in monetary terms; benefits are measured in health improvements. By dividing costs by benefits, one can obtain a cost-to-effectiveness ratio for each health intervention, and interventions can be ranked by these ratios. Although a CEA is typically an economic analysis performed by health economists, it is also a measure of one ethical criterion for the evaluation of health programs. Cost-effectiveness is not merely an economic concern, because improving people's health and well-being is a moral concern, and an allocation of resources that is not cost-effective produces fewer benefits than would have been possible with a different allocation. Producing more rather than fewer benefits for people is one important ethical consideration in evaluating actions and social policies.

Second, the allocation should be equitable or just; equity is concerned with the distribution of benefits and costs to distinct individuals or groups. The maximization of benefits, which is associated with the general philosophical moral theory of utilitarianism or consequentialism, however, is routinely criticized for ignoring those considerations (Rawls 1971). Equity in health care distribution is complex and embodies several distinct moral concerns or issues that this chapter delineates (Brock 2003a). There is no generally accepted methodology comparable to CEA for determining how equitable a distribution is; nevertheless, allocations are unsatisfactory if equity considerations are ignored.

Efficiency and equity can sometimes coincide. In some of the world's poorest countries, for example, health budgets support tertiary care and travel to clinics abroad for the elite and the well connected, even as the poor are denied effective, low-cost prevention or treatment for life-threatening diseases (Birdsall and Hecht 1995). Moreover, because equity concerns the relative treatment of different individuals, CEA is largely unobjectionable when it is used only for evaluating alternative health interventions that would serve the same patients. However, considerations of equity may conflict with cost-effectiveness and so may provide moral reasons for an allocation that is not cost-effective. The discussion in this chapter accepts that CEA identifies one important ethical criterion in evaluating health care interventions—producing the most benefits possible for individuals served by those interventions and then focuses on the other ethical criterion of ensuring equitable distribution of those benefits.

This chapter considers two types of equity issues: first, those that arise in the general construction of a CEA that is, in determining the form of a CEA; second, those that arise in the use of the results of a CEA for resource allocation in the health sector. It is worth noting that, when applied appropriately and broadly to all social conditions and programs that significantly influence health, CEA may often support using resources to affect the so-called social determinants of health which largely affect the incidence of disease, disability, and premature mortality rather than using those resources on health care to treat disease. However, we shall focus largely on CEA in the evaluation of health care and public health programs.

Issues in the Construction of a Cost-Effectiveness Analysis

Cost-effectiveness analyses require decisions about which costs to include, which if any financial gains should be counted as offsetting costs, whether to include benefits beyond the effects of the intervention on health, and whether all health gains should be valued alike. None of those decisions, in our view, is exclusively a technical issue, and CEA results reflect the analysts' ethical judgments on those issues.

Evaluation of Benefits. Evaluating health benefits within a CEA involves several issues. This chapter assumes that some version of a quality-adjusted life year (QALY) is used to combine the two main benefits of health care (a) protecting or improving health or health-related quality of life and (b) preserving life. Disability-adjusted life years (DALYs) are a variant of QALYs in that they measure the losses from disability or premature death; a CEA will determine which interventions will maximize QALYs or minimize DALYs. Calculating QALYs requires a metric evaluating the effect of different states of limitations in function on health-related quality of life, such as the Health Utilities Index (Horsman and others 2003). The Disease Control Priorities Project uses the health state valuations or disability weights of the World Health Organization (WHO). The relative value of any particular health state, typically on a scale in which "0" represents death and "1" represents full, undiminished function (or health) is generally determined by soliciting a group of individuals' preferences for life in that state using standard gambles, time tradeoffs, visual analog scales, or person tradeoffs. In all these methods, a common issue is whose preferences to use for valuing health states. The main debate has been whether to use a randomly selected group of citizens or to use people who have the particular disability or limitation in function being evaluated.

This issue matters because a number of studies have shown that persons without disabilities generally evaluate the quality of life with a particular disability as significantly worse than do persons who have that same disability (Menzel and others 2002). If the preferences of persons without disabilities are used, their lower evaluation of quality of life with various disabilities will mean that fewer QALYs will be produced by lifesaving interventions for persons with disabilities than if the preferences of persons with disabilities had been used. However, if we use the preferences of persons with disabilities, then both prevention and rehabilitation will receive less value than if the preferences of persons without disabilities had been used.

This difference in evaluations in part results from ignorance, prejudice, and stereotypes on the part of persons without disabilities about what it is like to live with various disabilities. The difference results as well from the process of adaptation to disability in which disabled persons adjust by learning new skills, cope by adjusting their expectations to their new circumstances, and accommodate by substituting new aims and activities for ones made difficult or impossible by their disabilities (Solmon and Murray 2002). They thus adopt a new valuational perspective for making health and quality-of-life evaluations. Because the adoption of this new perspective resulted from a disability, it will represent a set of values for making choices that reflects a restricted set of abilities. Nevertheless, neither the nondisabled perspective nor the adapted disabled perspective is mistaken; they are only different (Brock 1995). These differences create controversy in the literature over which perspective is correct for cost-effectiveness evaluations in health care.

A second issue is whether, in evaluating interventions that preserve or extend life, we should use life years saved (as QALYs do) or lives saved. Certainly individuals offered two interventions that would preserve their lives for different lengths of time would prefer, all other things being equal, the alternative with the longer period of survival. Moreover, when the differences are extreme for example, extending group A's lives by a week or extending an equally numerous group B's lives by 10 years virtually everyone would judge this difference to support giving priority to group B. This fact suggests that even the proponent of counting lives saved should require that the lives saved for a shorter period of time must still be saved for a significant period of time; what is significant will depend in part on the duration of lives saved by the alternative with which it is being compared. Some empirical studies indicate that ordinary people tend not to give much weight to differences in the duration of health benefits to different groups of persons when prioritizing between them, as long as the lesser duration benefits are viewed as significant; this attitude suggests that they favor lives saved over life years saved (Nord and other 1996). The life years saved versus lives saved controversy remains unsettled.

Should Life Years be Age Weighted? The standard assumption in most CEAs using QALYs is that one QALY has the same social value, regardless of the age of the recipient (Gold and others 1996). Thus, equality is adopted as the weighting for QALYs achieved by recipients at different ages, and that is the approach adopted in this volume. The use of any age weighting that gives less value to benefits for the elderly than for younger persons is often charged as unjust age discrimination. Even the use of equally weighted QALYs is often charged as unjust age discrimination because, other things being equal, saving the lives of younger persons will produce more QALYs than saving the lives of older persons. The goal of lives saved, as opposed to life years saved, removes this disadvantage to the elderly from CEAs that use QALYs. However, if the relevant benefit is adding years to life, then standard CEA is neutral or impartial regarding age, in the sense that it gives the same value to a year of life extension whatever the age of its recipient.

WHO, in its burden-of-disease and resource prioritization studies that use DALYs, rejected the equal age weighting that is standard with QALYs. Instead, it gave less value to DALYs prevented for infants, young children, and the elderly, in comparison with persons in their productive adult years. WHO justified this weighting by the fact that the very young and the elderly both tend to be economically, socially, and psychologically dependent on adults during those adults' productive working and child-rearing years (Murray 1994). This justification is ethically problematic, however, because it assigns different value to meeting people's health needs on the basis of differences in the instrumental value to others of meeting their needs. This approach differentiates people solely on whether they are a means to benefiting others. The same reasoning would justify giving priority to rich over poor patients with the same medical needs because the rich are more socially productive than the poor, a practice that would be widely regarded as unjust.

Writers in this field have provided different reasons for giving greater value to QALYs for younger patients, however, that are not subject to this moral objection and that are specifically grounded in fairness. For example, Alan Williams has developed an argument to the effect that fairness requires that individuals should each receive "fair innings" of QALYs in their lives (Williams 1997). In this view, the earlier a preventable death could occur and the worse a person's past health is, the greater is the unfairness the person suffers so the greater is the moral urgency, grounded in fairness, of preventing the death. The younger a person is, the greater is the moral value of providing a QALY to him or her. This view leaves open to what extent the moral value of QALYs should decline with the age of the recipient. This age weighting to favor the young has been attacked by some as unjust age discrimination, but because an explicit moral justification in terms of fairness is offered for it, critics must show why that justification is unsound.

What Costs Should Count in Health Cost-Effectiveness Analyses? No controversy surrounds the inclusion in a CEA of direct costs of a health intervention program or direct health benefits to the intervention's recipients. Ethical issues do, however, arise in other aspects of the cost calculation (Brock 2003b). A full CEA of alternative health programs should take account of all the economic effects on public or private expenditures of the alternative health interventions or programs under analysis. An example is provided in the consideration of treatment for two alternative health conditions judged to have equally detrimental effects on patients' health: the first condition permits patients to continue working, and the second interferes with regular work and so has large economic costs to the patients' employers. Should the costs of treating the second be reduced by the cost savings to the employers from returning the patients to work on a regular basis? If so, the second treatment program will have a more favorable cost-effectiveness ratio than the first, even if it may be no better or worse without consideration of those economic effects. The same issue arises in many other contexts.

From the moral perspectives of both a consequentialist and a standard CEA, these indirect economic effects for others are real benefits or cost reductions and should be part of the CEA. The fundamental moral objection to giving higher priority to treating those who can be treated at lower net cost because of the economic savings to their employers is the same as that with WHO's instrumental rationale for its age weighting. One condition or group of patients gets higher priority solely because treating it or them is a means to producing economic benefits to others, thereby reducing the net social costs of their treatment. This approach violates the Kantian injunction against treating people solely as means—the first group has lower priority for treatment solely because treating that group is not a means to the economic savings to employers. It fails to give equal moral concern to the health needs of each group of patients because it discriminates against the less socially valuable patients. Conversely, at the macro level of the allocation of resources to health instead of other social goods, the WHO Commission on Macroeconomics and Health has supported increasing health investments in developing countries because such investments often more than pay for themselves in their economic and development benefits (CMH 2001). Using a "separate spheres" view, only the health benefits and health costs of alternative health interventions should determine their priority for obtaining resources, but this view remains controversial.

Another aspect of cost calculation concerns whether future health care and other costs, such as old-age payments, that will be incurred as a result of a person's life being saved should be added to the costs of treating that person now. Persons who do not die now because of a life-saving intervention will typically go on to incur future health costs that would not have been incurred had they died now. The U.S. Public Health Service Panel on cost-effectiveness recommended that inclusion of these costs be optional in CEAs (Gold and others 1996). Others have argued that, if CEA is designed to maximize lifetime utility, the future costs should be included (Meltzer 1997). These are costs that would not be incurred if the patient was not saved, but virtually no one would argue that, because of those costs, we should judge a life-saving intervention as not cost-effective and thus deserving of lower priority than interventions that do not have those effects. What does this thinking show? That we are not prepared to allocate health

resources on the basis of a full CEA that accounts for all the costs incurred and saved by those interventions that is, that some should be disregarded on ethical grounds.

Should Health Benefits and Costs Be Discounted in Cost-Effectiveness Analyses? As standard practice in CEAs, both health care costs and benefits are discounted at the same rate, for example, 3 percent or 5 percent, and the Disease Control Priorities Project applies a 3 percent discount rate to costs and benefits (Gold and others 1996). Little controversy surrounds the idea that future monetary costs and benefits should be discounted to their present value in a CEA. The same amount of money is worth more if received today than in 10 years because it can be invested at the market rate of interest if received today. For the same reason, costs that can be deferred require fewer present dollars to meet them.

The controversial issue is whether health benefits should be discounted that is, whether the same magnitude of health benefit has progressively less social value the farther into the future it occurs. This issue is complex and has engendered an extensive literature that cannot be reviewed here, but we can at least try to focus the issue. It is appropriate to discount for the uncertainty about whether potential beneficiaries will survive to receive a future health benefit and to discount for any increased uncertainty about whether a benefit will occur because it is more distant. However, these uncertainties are reflected in the calculation of expected future benefits and do not require that future benefits be discounted. Likewise, if individuals receive a health benefit (such as regaining mobility) sooner rather than later, their total lifetime benefit may be greater, but this fact, too, is reflected in the estimation of the total benefit without discounting.

The ethical issue about discounting is whether, after taking account of such considerations, a health benefit of the same size has progressively less social value the farther into the future that it occurs. To make the issue more concrete, suppose we must decide between two programs: one will save 100 lives now, and the other, say a hepatitis vaccination program, will save 200 lives in 30 years. The vaccination program will save twice as many lives, but if we apply even a 3 percent discount rate to the future lives saved, they are equivalent to only 78 lives saved now, and we should prefer the first program. This example illustrates not only the theoretical issue, but its practical import, too, because discounting future health benefits will systematically tend to disadvantage prevention programs that must be undertaken now but whose benefits occur only at some point in the future. This reasoning applies not only to many vaccination programs, but also to most programs to change unhealthy behaviors in which the benefits generally occur at some later time.

Arguments for discounting health benefits at the same rate as costs have included consistency arguments (Weinstein and Stason 1997), avoidance of paradoxes in allocation concerning research and deferral of spending (Keeler and Cretin 1983), individual or social rates of time preference, and so forth. Those arguments cannot be reviewed here, but whether to discount health benefits is squarely an ethical question about the valuing of health benefits over time and should be explicitly addressed as such in allocating resources.

Issues in the Use of Cost-Effectiveness Analysis for Resource Allocation

It is now widely recognized that CEA alone is not a satisfactory guide to resource allocation in all cases. CEA, as customarily formulated, measures the sum of costs and benefits and largely ignores the pattern of their distribution across the affected population. In some cases, the resulting allocation will strike most observers as unfair. Health resource allocators need to take distributional issues into account along with cost-effectiveness.

Priority to the Worst Off. Justice requires a special concern for the worst off, as is reflected in aphorisms such as "you can tell the justice of a society by how it treats its least well-off members," in the well-known Difference Principle in John Rawls's theory of justice, and by the special concern for the poor

within many religious traditions (Brock 2002; Rawls 1971). This concern is often understood to reflect a concern for equality in particular, equality in outcomes or welfare between people. In the health context, it takes the form of a concern for reducing inequalities in health between persons or groups. A variety of ethical bases underpin a concern for equality in general and for equality in health in particular, and they cannot be explored here. It is important, however, to understand that concern for the worst off is different from a concern for equality, because the two can be and often are confused. Raising the position of the worst off will typically reduce inequality, but it need not always do so. Sometimes improving the position of the worst off may unavoidably improve the position of those who are better off even more and thereby increase inequality. Moreover, the concern for equality in outcomes is subject to the "leveling down" objection, in which equality is achieved by making the better-off members worse off, even when doing so in no way benefits those who are worst off. In the face of that objection, many have rejected equality in outcomes in favor of a prioritarian view, according to which benefiting people has greater moral value the worse off those people are (Parfit 1991).

A number of possible lines of reasoning support prioritarianism. For example, the worse off that people are, the greater is the relative improvement that a given size of benefit will provide them, so the more the benefit may matter to them. Alternatively, the greater the undeserved health deprivation or need that an individual suffers, the greater is the moral claim to have it alleviated or met.

However priority to the worst off is justified, an important issue is who the worst off are. In the context of resource allocation in health care, the worst off might be those who are globally worst off, those with the worst overall well-being (such as the poor), or those with the worst health (that is, the sickest). General theories of justice usually focus on people's overall well-being, often allowing a lower level in one domain of well-being to be compensated for by a higher level in another domain. However, there are both moral and pragmatic reasons for what has been called a separate spheres view, according to which the worst off for the purpose of health resource allocation should be considered to be those with worse health. Morally, for example, Scanlon has argued that "for differences in level to affect the relative strength of people's claims to help, these differences have to be in an aspect of welfare that the help in question will contribute to" (Scanlon 1997, 227). Pragmatically, it may generally be too difficult, costly, intrusive, and controversial, as well as too subject to mistake and abuse, to have to inquire into all aspects of people's overall levels of well-being.

Even if health allocation to the worst off should be based on levels of health, other issues remain. For example, are those with worse health those who are sickest now, at the time a health intervention would be provided for them, or those with worse health over time, taking into account past and perhaps expected future health? The latter would give special weight to meeting the health needs of those with long-term chronic diseases and disabilities. Separate spheres would still include past and future health. Should special priority also be given to those whose health is not worse now but is especially vulnerable to becoming worse?

Finally, how much priority should the worst off receive? Giving absolute priority to the worst off is implausible because it faces the bottomless pit problem—using very great amounts of resources to produce very limited or marginal gains in the health-related quality of life of the severely ill or disabled. However, there is no apparent principled basis for determining how much priority the worst off should receive.

Aggregation and Cost Differences. The aggregation problem occurs when determining at what point small benefits to a large number of persons should take priority over very large benefits to a few, because the former result in greater aggregate or total benefits (Daniels 1993; Kamm 1993). The issue can be illustrated by the initial effort to prioritize different treatment-condition pairs in the Medicaid program in the U.S. state of Oregon by what was essentially a cost-effectiveness standard. As was widely reported,

capping teeth for exposed pulp was ranked just above performing appendectomies for acute appendicitis, even though appendicitis is a life-threatening condition. A variety of methodological problems affected Oregon's analysis, but this kind of result is to be expected from CEA. The Oregon Health Services Commission estimated that it was possible to provide a tooth capping for more than 100 patients for the cost of one appendectomy, so the aggregate benefits of the many tooth cappings were estimated to exceed the benefit of one appendectomy. As a consequence of results of this sort, the commission fundamentally changed its prioritization methodology to largely ignore cost differences, except in the case of roughly equally beneficial interventions. The commission essentially adopted what might be called a relative effectiveness or benefit standard (Hadam 1991).

What Oregon's experience shows is that most people's sense of priorities is determined by a one-to-one comparison of the benefits of different interventions, in which case appendectomies are clearly a higher priority than tooth capping. That ignores the great differences in costs between different health interventions that a CEA will reflect. Is it then simply a mistake to ignore those cost differences in allocating health resources? At least two moral considerations suggest not. First, empirical studies have shown that many people ignore the cost differences because they believe that patients should not be at a disadvantage in priority for treatment simply because their condition happens to be more expensive to treat than are other patients' conditions (Nord and others 1995). Second, according to many moral theories, individuals should confront other competitors for scarce resources as individuals, and their priority for treatment should be determined by the urgency of their individual claims to treatment (Scanlon 1997).

Then again, most people and most moral theories do not reject all aggregation of different sizes and costs of health benefits in setting priorities and allocation, although there is no consensus either on when aggregation should be permitted or for what reasons. However, at a minimum, we suggest that individuals should not be denied very great health benefits in the extreme case, life-saving interventions merely to provide small health benefits to a large number of other persons.

Fair Chances and Best Outcomes. The thesis that resources should be targeted to interventions in which they will do the most good ascribes a higher priority to those who can be helped more easily or cheaply. This thinking, in turn, implies that some patients will lose out simply because their needs are more difficult or expensive to meet. Consider, for example, a ward with 100 patients, 50 of whom require one pill and 50 of whom require two pills to recover. The patients are otherwise similar. The clinic has 50 pills and must decide how to distribute them. To achieve the best outcome, all 50 pills should be given to the patients who need only one to recover. However, to give each patient an equal chance to recover, entitlement to treatment should be awarded randomly. Seventeen fewer cures would result.

Limited surveys indicate a sharp difference between health professionals and the general public in their responses to this conflict. Most health professionals favor distribution to one-pill patients only, and most members of the general public insist that people should not be penalized for needing two pills (Nord 1999). This division of opinion goes to the heart of CEA, which is precisely a guide to identifying the route to the best outcomes that can be hoped for with existing resources. It also creates a dilemma for those health professionals who maintain that health policy should be based on values most frequently endorsed by the population affected.

The conflict between fair chances and best outcomes arises not only from differences in the costs of treating otherwise similar groups of patients, but also when one group of patients will receive somewhat greater benefits than another at the same cost. The appeal of a fair-chances solution is greater when the difference in cost-effectiveness between the two programs is relatively small compared with the potential gain or loss to individual patients. Suppose that health program A will produce 5,000 QALYs while program B will produce 4,500 QALYs and that the effect on the health or life of each patient served is

large in the extreme, life saving. Patients who would be served by program B could complain that it is not fair that all the resources go to program A and none to B when they have nearly as pressing health needs and would be benefited by treatment nearly as much as the patients served by program A. If all cannot be treated, they might go on to argue, they deserve a fair chance to have their needs met rather than having no chance for treatment only because treating them would produce slightly less benefit than treating the patients served by program A. The small difference in benefits produced for the two groups—for example, a slightly greater life expectancy or more serious disability averted in program A they argue, is too small to justify the tremendous difference in how the two groups are treated. In the extreme case, some live and others die. The better outcome is produced by funding program A rather than program B, but that additional good is insufficient to justify morally the huge difference in the way the two groups of patients are treated. The conflict between fair chances and best outcomes can arise in a variety of contexts (Kamm 1993).

Preferring the most cost-effective program can also seem unfair because it compounds existing unfair inequalities. For example, screening slum-dwelling black men for (hypertension) targets the group with the highest incidence and greatest risk of premature death. However, it is more cost-effective to target well-to-do suburban white men, because they have more ordered lives, comply better, have personal doctors and the means to obtain medical services, are more educated, and are more likely to modify their lifestyles wisely. However, if the poor black men are not screened for this reason, it only compounds their existing unjust deprivation and, of course, is also in conflict with giving priority to the worst off.

If those who need a less cost-effective program deserve a fair chance to have their needs met, what would be a fair chance? Some argue that a fair chance is an equal chance, so some random method of selecting which program to fund should be used (Broome 1991). Others suggest proportional chances or a weighted lottery, in which the chance of each program being selected is proportional to the amount of health benefit each would produce, as a way of balancing fair chances against best outcomes (Brock 1988). Alternatively, some resources might go to each program (which is usually possible at the macro level), thereby benefiting some patients in each group at least if their relative benefits are not strikingly dissimilar instead of all going to the most cost-effective programs.

Another consideration supports spreading some resources to less cost-effective programs instead of devoting them all to the most cost-effective: to give all or at least more patients a reason to hope that their health needs will be met. This consideration may be especially important in developing countries where resource scarcity is more severe and adhering strictly to cost-effectiveness criteria could result in large numbers of patients with serious or even life-threatening health needs having no hope that their needs will be met.

Discrimination Against Persons with Disabilities. The use of CEA in resource allocation to maximize the QALYs produced by available resources will often discriminate against persons with disabilities. Many persons with disabilities such as cystic fibrosis, HIV/AIDS, and chronic pulmonary or heart disease have reduced life expectancies or health-related quality of life as a result of their disabilities. Life-extending health care for those people will produce fewer QALYs than for people without them, all else being equal.

When health interventions are aimed at improving quality of life rather than extending life, similar discrimination can arise. The presence of disabilities can act as comorbidities, making treatment less effective or more expensive (or both) than it would otherwise be, thereby worsening its cost-effectiveness ratio relative to comparable treatment for persons without disabilities. These effects of treatment can result from a disability that exists before treatment and is unrelated to the treatment provided. So it seems that a cost-effectiveness standard for resource allocation discriminates against such persons specifically because of their disabilities. Moreover, this effect will arise not only in the case of preexisting disabilities,

but also in the case of patients who become disabled as a result of treatment that is only partially effective.

Several strategies to avoid this discrimination in resource allocation have been suggested. Perhaps the most plausible, at least for the case of life-sustaining treatment, is to ignore differences in patients' post treatment quality of life as long as each patient accepts and values that quality of life and to ignore differences in life expectancy after treatment as long as each will receive a significant gain in life extension; obviously, what counts as significant is vague and needs finer definition. Ignoring differences in life expectancy post treatment fits with empirical evidence that individuals give little weight to duration of benefits in prioritizing between health interventions that serve different individuals.

Cutoffs for Cost per Quality-Adjusted Life Year. It is not uncommon in health care allocation to suggest the use of cutoffs tied to cost per QALY, although the cutoffs suggested vary substantially depending on the overall wealth of the country and on the amount that it spends on health care. The cutoffs can be of some value in identifying health interventions that are either good or poor buys, given the society's overall wealth and overall level of health spending. However, it is important to be clear that such cutoffs should never function as anything more than a rough initial guide in health resource allocation. The various equity considerations discussed briefly above can serve as justification for departing from or violating any cutoffs related to cost per QALY.

Responsibility for Health Needs. Some have suggested that health needs for which individuals are morally responsible should have lower priority than health needs for which individuals are not responsible (Moss and Siegler 1991). If individuals are responsible for their health needs and could have taken steps to avoid them, they have weaker claims on social resources to meet those needs than do individuals whose health needs are no fault of their own and could not have been prevented. Smoking and substance abuse are two of the most prominent examples of behaviors often cited. However, differentiating patients by whether they deserve care on the basis of whether they are responsible for their health needs does not fit the practice or norms of medicine, which have the goal of meeting patients' medical needs.

There are strong moral reasons for considerable caution in letting health resource allocation depend on individuals' responsibility for their health needs (Wickler 2002). For that practice to be fair to those whose needs receive lower priority because of behavior, (a) the needs must have been caused by the behavior, (b) the behavior must have been voluntary, and (c) the persons must have known that the behavior would cause the health needs and that if they engaged in it their health needs resulting from it would receive lower priority. Smoking shows that these conditions are not easily satisfied. Smoking is one causal factor in much cancer and heart disease, but many smokers do not get those diseases, indicating that other factors, no doubt in part genetic differences for which individuals are not responsible, also play an important causal role. Smoking is typically begun when individuals are young adolescents, and as discussed in chapter 46, it is highly addictive, which undermines the voluntariness of continuing to smoke. Individuals in industrial countries are now generally familiar with the health risks of smoking, but this is less true among less educated populations in developing countries, where smoking is an increasing problem. No one anywhere has been informed before they smoke that, if they do, their health needs from smoking will receive lower priority for treatment than will other health needs.

Thus, it would generally be unfair to give smokers lower priority for treatment of smoking-related diseases on the grounds that they were morally responsible for those health needs, although there may be other behaviors for which individuals could more justifiably be held responsible. Moreover, attempting to make those judgments in individual cases would be extremely difficult and controversial. Given the difficulty of instituting a fair practice that allocates health resources according to people's moral responsibility for their health needs, we generally have good moral reason to preserve the egalitarian

feature of the practice of medicine that looks to patients' needs for care rather than to whether they deserve care.

Ethics in Research and New Product Development

All new drugs and other medical products must be tested on human subjects before they are sold. Although participation in health research is often a valuable opportunity for participants, what happens to them is determined not only by their clinicians' therapeutic intent (if any) but also by the need to ensure that the research yields useful information. Managing the potential conflict between those motivations is often an ethically challenging task, and the issues become particularly contentious when research is conducted in developing countries.

Developing Consensus on Ethics and Human Subjects Research. The central ethical question in health research that involves human subjects is what may be asked of some individuals so that others may benefit. The question arises in any research in which human subjects are asked to participate, but is most pressing if the care that is offered to subjects provides no therapeutic benefit or if that care is compromised by the requirements of the study design. Informed consent, while in most cases a requirement for ethical justification of research involving risk, does not relieve the scientist of responsibility. The ethical question is what potential subjects may be recruited for, even if they do consent.

A rough consensus exists worldwide on the elements of research ethics and, increasingly, on the central role of the ethical review committee, or institutional review board (IRB). This consensus can be traced back to the post–World War II international determination to ensure that the kind of barbaric research practiced by Nazi scientists would not again stain the good name of medical science.¹ Three advisory documents have been particularly influential. The Nuremberg Tribunal that conducted the postwar Doctors' Trial promulgated a code of conduct for medical research that stressed the requirement of informed consent. The World Medical Association issued the first version of its Declaration of Helsinki in 1964 and has revised it several times. A further set of guidelines, issued in 1993 and revised a decade later, was published by the Geneva-based Council for International Organizations of Medical Sciences. Although they lack the force of law, these documents are widely acknowledged as international standards. Indeed, the World Medical Association's periodic revisions of the Declaration of Helsinki have become focal points for international debates over outstanding issues in research ethics.

The most elaborate codification of research ethics is the so-called Common Rule of Conduct of the U.S. Code of Federal Regulations (title 45, section 46), which derived from the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavior Research of the mid 1970s. In addition to proposing rules governing many aspects of research with human subjects, the commission proposed that the IRB be given the central role in research ethics and be responsible for prior review of research proposals.² The IRB was a compromise, granting a measure of self-regulation to scientists and an assurance of ethical conduct to the government and the public for publicly funded investigations.

The basic elements of research ethics engender little disagreement. The research must never be brutal or inhumane, and all unnecessary risks should be eliminated. Any net risks to subjects must be justified by the prospect of potential benefits to others. Prospective participants must be told that they are in a study and must be informed of its nature and its risks and benefits. In the case of research that offers therapeutic benefit, scientists must explore the range of reasonable therapeutic alternatives with the patient. Potential subjects must understand that their participation is completely voluntary and that they may withdraw at any time and for any reason. Because they cannot voluntarily shoulder risks, further protection must be provided to those who cannot give consent. Such people include, among others, mentally incompetent or immature participants and those involved in research (chiefly in social psychology) that requires initial

deception. Consent, however, is not sufficient to ensure fairness; there should be additional safeguards against unfair distribution of the burdens and benefits of research. Finally, all research that involves potential risks should be reviewed by an IRB acting on the basis of internationally recognized ethical principles.

The global acceptance of these principles and the rapid development of capacity for ethical review attest to the perceived validity of this system of rules and procedures of ethical review. However, there has been relatively little research on how IRBs actually perform. Many IRBs in smaller institutions lack the necessary expertise to review novel or complex proposals, and their institutional setting creates a potential conflict of interest. Government investigations of the adequacy of IRBs for the tasks that are now assigned to them have often been critical (for example, Office of the Inspector General 1998, 2000). IRBs are often overworked and understaffed, resulting in ever-lengthening delays between initial submission of protocols and final approval. Regardless of the value of IRBs, predicting what will pass through them and what might provoke delay or rejection has become a significant concern for medical researchers. The system thus has costs as well as benefits, a fact that lends additional gravity to the controversies that it must resolve.

Goals of Ethical Review of Research. Although the overall purpose of ethical review is to ensure that research with human subjects is ethically defensible, the international consensus specifies several distinct goals that are sometimes in tension with each other:

- *Protection.* Ethical review committees can protect subjects by alerting investigators to unforeseen hazards and by suggesting research designs that can avoid unnecessary risk or reduce the number of subjects exposed to risk. By insisting that a clear explanation of risks and benefits be provided to potential participants, ethical review committees also help potential participants to protect themselves. Ethical review committees often take the name "Committee for the Protection of Human Subjects," reflecting a central preoccupation of research ethics today.
- *Assurance that participation is voluntary.* Some research cannot be conducted without asking some participants to endure discomfort or pain, to delay relief from symptoms of their disease, or to risk other harm so that future patients may benefit. Permitting investigators to approach potential subjects in these cases requires an ethical judgment. In approving such a proposal, the function of the ethical review committee is not, strictly speaking, only to protect the subjects (the goal of protection would often be served more effectively by declining to do the research), but also to permit them to be enlisted in the effort to improve health care for others. Thus, a second function of ethical review is to ensure that those who agree to participate do so voluntarily and freely and that they understand what is being asked of them.
- *Equality and fairness.* Although research ethics committees have little authority to address persistent social injustices, a third concern of research ethics is that the benefits and burdens of health research be distributed fairly. This function receives relatively little attention in the literature of research ethics, despite its prominence in such well-known documents as the Belmont Report of the National Commission for the Protection of Human Subjects (1979). Many of the most notorious abuses of research subjects, including the Nazi investigations in the concentration camps, the Japanese biowarfare experiments on Chinese and other civilians, and the Tuskegee research on African Americans suffering from syphilis, were committed on subjects chosen exclusively from disadvantaged groups.

Those three goals of ethical review protecting subjects; ensuring voluntary, informed participation; and reviewing the fairness of recruitment are promulgated in the international guidelines and in the Common Rule (and in the regulations of other countries), but they do not always point in the same direction. For

example, a research project that asks participants to endure a burden or risk thus failing to offer full protection can still meet the requirement of equality if the burden is equally shared.

Ethical review, thus, is not a matter of applying a checklist, but it imposes an obligation of substantial ethical judgment. A key challenge for IRBs is to earn and retain the trust of participants and of the public, a task made more difficult by the unavoidable absence of explicit criteria for approval. This problem is exacerbated by the institutional conflict of interest inherent in the placement of the IRB within the research institution, which prompts concern that the committees will downplay risks to subjects for projects that profit or benefit the institution or its influential staff members. Conversely, IRBs that are fearful of institutional embarrassment or legal sanction in the event of any harm befalling research participants might lean too far in the direction of overprotection of subjects, at the expense of important scientific research initiatives. Both concerns have been raised about the IRB system.

Current Controversies in Research Ethics. Some of the most sharply disputed issues have arisen in international collaborative research involving scientists and sponsors from wealthy countries conducting experiments in developing countries. Some of the problems are procedural. For example, U.S. agencies have insisted on the same kind of recordkeeping for IRBs in developing countries that is required of IRBs in U.S. research institutions. IRBs in developing countries may accept the same principles of accountability, but they do not have the elaborate staffs and budgets that leading IRBs rely on.

The most difficult disputes involving the ethics of research in developing countries are, however, substantive rather than procedural.

Standard of Care The international guidelines used in navigating the ethical dilemmas of research in developing countries were created for the very different purpose of ensuring that what happened at Dachau and Auschwitz would not recur. It is not clear whether those rules usefully resolve the kinds of dilemmas that arise in, say, Uganda or Peru.

The Declaration of Helsinki, following the Nuremberg Tribunal, requires informed consent of all competent research subjects, and in section 29 states that "the benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."

To its supporters, any departure from the letter of the Declaration of Helsinki that would permit an experiment in a poor country that would be forbidden in a rich one would constitute a double ethical standard. In their view, this clause of the Declaration of Helsinki affirms the equal importance of human lives, regardless of wealth or nationality, and stands as a safeguard against exploitation of those made vulnerable by poverty, sickness, and absence of governmental protection.

Opponents, however, argue that this position seems to rule out the possibility of testing cheap new products that may be effective, although perhaps not as effective as other products that the population could not afford. If so, it would be difficult to understand whom the single-standard-of-care position would be protecting, for surely it is better for a seriously ill person to receive a good drug, even if it is not the best, than to receive no drug at all.³

Both points of view deserve respect. The single-standard approach is consistent with the postwar consensus on principles of research ethics, and it offers a bright line between research that amply respects human subjects and that which might result if sponsors and scientists were tempted to roam the globe in search of human subjects who could be used as experimental material with a minimum of expense or trouble.

Opponents of the universal-standard view, however, challenge its premise. It made sense to insist on a single, universal standard when the problem was Nazi barbarity, because the prevailing standard was high and the medical criminals in the death camps denied it to the imprisoned minority people unjustly stripped of their entitlements. In Uganda or Nepal, however, care at the highest world standard is available, if at all, to only small elite.

A full reconciliation of those points of view may not be possible. The authors suggest that a relativized standard should be considered only when the beneficiaries will include the impoverished, sick population. Even in those cases, however, the local standard of care could be adopted in the experiment only if it met or exceeded the standard provided by other countries at similar levels of development.

Placebo Controls and Other Issues Involving Research Design For certain purposes, scientists use a placebo control even though a proven treatment exists. Patients in these control groups thus receive care that is inferior to what they would experience in good clinical care. Until very recently, the Declaration of Helsinki flatly condemned this practice (its current language is somewhat less restrictive), but the U.S. Food and Drug Administration (FDA) accepted results of these trials in applications for approval of new drugs. The FDA's justification for this acceptance rests on two claims, one scientific and one ethical. The first is that in certain contexts (for example, for conditions such as depression, in which eligibility criteria and outcomes are subjective, to an appreciable extent, and in which symptoms fluctuate in both treated and untreated patients), active controls may produce misleading indications of equivalency, yielding seemingly positive results that may be spurious. The second is that when only placebo controls can be informative, it is sometimes justifiable to ask participants to be randomized with placebo and thereby to risk discomfort and distress (but not any appreciable risk of death or long-term impairment).

Debates over placebo controls are often joined in the context of disputes over the appropriate standard of care that arise in the case of research in developing countries, but placebo controls are controversial in trials in high-income countries, too. Placebo controls are one instance of a large category of ethical issues in research that require weighing the importance of a scientifically ideal research design against the well-being of participants. For example, a study of long-term chemotherapy to prevent the recurrence of breast cancer was halted before the designated endpoints had been reached after the study's Data Safety and Monitoring Board decided that continuing the study after a strong trend had been established favoring the chemotherapy would be unfair to the control group. It is notable that in this instance severe criticism of this decision was voiced by an organization representing women at risk for breast cancer, as well as by the editorial board of the *New York Times*. Critics of the early termination of the trial were, in effect, aligning themselves with the interests of future beneficiaries of the research and possibly against the immediate interests of the women in the control group.

Rights of Host Communities Ideally, research involving human subjects would be a cooperative endeavor for mutual advantage among free citizens who understand and endorse the need for research and who expect to share both in the burden of serving as research subjects and in the eventual benefit of improved health care. Societies that recruit subjects primarily from lower socioeconomic strata fall short of this ideal; those that do not offer new advances in care to all of their citizens fall even further short, raising serious questions about fairness. Furthest of all from this ideal are some instances of the increasingly common practice of recruiting research subjects among the poorest people in the poorest countries. The means for protecting human subjects in these countries are often nonexistent. Most of their citizens will be unable to afford new drugs developed by firms in industrial countries. It is not clear that these subjects participate voluntarily. Their lack of scientific education or even literacy limits their ability to understand the terms of the proposed agreement with the scientists and sponsors (particularly when consent forms, on legal advice, run to 20 dense pages), and poverty often deprives them of any alternative means of recovering their health.

Despite these potential ethical shortcomings, international collaborative research is assured of continued growth. Some of this research targets diseases affecting mainly poor people, who as a group suffer more from too little research on their populations than from too much. Even research intended to develop therapies that will be affordable only to much wealthier patients can be defended. Individual participants may receive better care than they would otherwise, and visiting scientists offer employment and technical training.

To right the perceived imbalance in what is asked of research subjects in poor countries and the value that is obtained by scientists who experiment on them, some have proposed that sponsors of research in the poorest countries compensate their hosts by offering a supplementary benefit (Glantz and others 1998). One much discussed option is access following the end of the study to any drugs or other therapies whose effectiveness is confirmed in the research. The most limited proposals would restrict this entitlement to individuals who were enrolled in the study (those who received placebo as members of a control group, for instance), and time limits (such as three years) have been proposed in the case of chronic diseases such as HIV/AIDS. More expansive community benefit proposals have called for lifetime access to the treatments by all participants, their families, other members of the local community, or even all citizens of the country. Other proposed benefits include a specified amount of technology transfer, including scientific training and the construction of clinics and laboratories, and cash payments earmarked for health care. A moderate proposal is to encourage these benefits but to require only that they be discussed and agreed on before investigations are initiated (National Bioethics Advisory Commission 2001).

These proposals are intended to restore fairness to the relationship between participants and those who benefit from research, including scientists and their sponsors and also future beneficiaries of advances in medical science. Among the potential drawbacks are the inability to specify, even roughly, how much is owed to host communities; the inability to determine whether community benefit should be required even of research funded by governments or philanthropists for the benefit of people living in the host communities; and the risk that placing these demands on proposed research projects will drive them away from these very needy sites. Some of these uncertainties may be resolved over time as a variety of approaches are attempted, particularly if they are studied and reported to officials in potential research sites.

These international collaborations would draw less scrutiny if it were clear that all subjects knew what they were getting into and participated of their own free will. Although evidence on this point is mixed, special circumstances in some countries introduce problems that will have to be addressed over the long run. Cultural differences between host populations and scientists may lead to conflicts over who has the authority to speak for the individuals invited to participate in a given study. Regulatory authorities in high-income countries have been reluctant to accept permission by a woman's husband or by a village chief on behalf of his people in lieu of individual consent. It is often unclear particularly from the vantage point of an IRB in Europe or the United States whether the cultural norms of the host population designate the husband or village chief as decision makers in these transactions and whether insistence on concurrent individual consent would be viewed as intrusive or insulting.

Another recurring issue is whether people enrolled in a trial of a promising therapy who are ill and very poor can rightly be viewed as volunteers. The prospect of a cure for a person who would otherwise die would seem to be irresistible, even if the treatment is not up to the standards that even less well-to-do citizens of richer countries would expect. Financial incentives, too, would predictably have a powerful effect on an individual who may always be looking for a day's wage to feed hungry children. Some IRBs limit payments to compensation for lost wages and travel expenses, but even at this level researchers are asked to change the amounts offered to avoid forcing a choice on the potential participant. As with alleged cultural differences regarding individual informed consent, IRBs operate with scant evidence on this point. It is difficult from a long distance to decide what amount of compensation undermines freedom

of choice. It is also unclear whether the moral categories used in these disputes have been adequately thought through. The fact that a poor person finds an attractive offer irresistible will be viewed as evidence of coercion by some observers but nothing more than common sense by others.

Most of these controversies can be traced back to underdevelopment and the inequalities of wealth and education that prevail among and within nations today, but progress in resolving the ethical controversies that have become obstacles to badly needed health research must be made even as these disparities persist. Viewing health research in the context of development and emphasizing research that is targeted to the needs of the poor majorities in poor countries can provide a context in which trust rather than fear or suspicion is the default response in host countries. Efforts to build capacity for ethical review within the host countries, such as financial support for ethical review committees, can place the locus of decision making closer to the people who serve as subjects. Research on the effectiveness of current ethical and regulatory requirements and mechanisms might enhance the process of ethical review while reducing its bureaucratic burden. Meanwhile, the quality and appropriateness of ethical review of this research that takes place in the sponsors' countries would be enhanced by eliciting the views of officials in developing countries, clinicians, scientists, and community leaders.

Notes

1. Because our current system of ethical review and regulation of research with human subjects derives from our resolve to prevent the recurrence of earlier abuses, it deserves mention that the standard historical account of research ethics has been seriously incomplete. While the Allies sat in judgment of the Nazi scientists at Nuremberg, abuses of similar scope and savagery practiced by Japanese biowarfare researchers on Chinese and other civilians and prisoners of war were kept secret (and their perpetrators were unpunished) following a pact with the criminal scientists to exchange data for war crimes immunity. Moreover, the Allied governments did not always honor the Nuremberg principles. In the Soviet Union, scientists attempting to develop for clandestine operations poisons that would not be identified on autopsy practiced their craft, with predictably lethal results, on hapless prisoners (Birstein 2001). Abuses in the United States, such as the Tuskegee syphilis study (Brandt 2000), have been more widely publicized, but ethical lapses in large-scale Cold War–related studies, ranging from radiation studies on urban populations (Advisory Committee on Human Radiation Experiments 1995) to surreptitious administration of mind-altering drugs such as LSD (Rockefeller Commission 1975), were state secrets.

2. In the United States, the Office of Human Research Protections, an agency of the Department of Health and Human Services, has overall responsibility for oversight of IRBs administering research using U.S. government funds. Its website is <http://ohrp.osophs.dhhs.gov>.

3. Supporters of the single-standard view might point out that, in its current version, the Declaration of Helsinki does not require that everyone in an experiment receive the best available care, but rather that new treatments be tested against the best available care. But this defense faces further objections. In some cases, testing against the best available care (rather than against the care currently provided to the population or against placebo) will fail to provide the evidence needed to convince the ministry of health or potential donors that funds should be provided. There is a potential contradiction in any view that claims both that all patients in experiments deserve the best care and that it is ethically acceptable to test a new treatment that is not expected to be quite as good as the best currently available.

References

1. Advisory Committee on Human Radiation Experiments. 1995. Final Report. Washington, DC: U.S. Government Printing Office.
2. Birdsall, N., and R. Hecht. 1995. "Swimming against the Tide: Strategies for Improving Equity in Health." Human Capital Development and Operations Policy Working Paper 55, World Bank, Washington, DC.
3. Birstein, V. 2001. *The Perversion of Knowledge: The True Story of Soviet Science*. Boulder, CO: Westview.

4. Brandt, A. 2000. "Racism and Research: The Case of the Tuskegee Syphilis Experiment." In *Tuskegee's Truths: Rethinking the Tuskegee Syphilis Study*, ed. S. M. Reverby. Chapel Hill, NC: University of North Carolina Press.
5. Brock, D. 1988. "Ethical Issues in Recipient Selection for Organ Transplantation." In *Organ Substitution Technology: Ethical, Legal, and Public Policy Issues*, ed. D. Mathieu. Boulder, CO, and London: Westview.
6. ———. 1995. "Justice and the ADA: Does Prioritizing and Rationing Health Care Discriminate against the Disabled?" *Social Philosophy and Policy* 12 (2): 159–84.
7. ———. 2002. "Priority to the Worst Off in Health Care Resource Prioritization." In *Medicine and Social Justice*, ed. M. Battin, R. Rhodes, and A. Silvers. New York: Oxford University Press.
8. ———. 2003a. "Ethical Issues in the Use of Cost Effectiveness Analysis for the Prioritization of Health Care Resources." In *Making Choices in Health: WHO Guide to Cost-Effectiveness Analysis*, ed. T. Tan-Torres Edejer, R. Baltussen, T. Adam, R. Hutubessy, A. Acharya, D. B. Evans, and C. J. L. Murray. Geneva: World Health Organization.
9. ———. 2003b. "Separate Spheres and Indirect Benefits." *Cost-Effectiveness and Resource Allocation* 1 (1):4.
10. Broome, J. 1991. "Fairness." *Proceedings of the Aristotelian Society* 91 (1): 87–102.
11. CMH (Commission on Macroeconomics and Health). 2001. *Macroeconomics and Health: Investing in Health for Economic Development*. Geneva: World Health Organization.
12. Daniels, N. 1993. "Rationing Fairly: Programmatic Considerations." *Bioethics* 7 (2–3): 224–33.
13. ———. 2000. "Accountability for Reasonableness." *British Medical Journal* 321: 1300–1.
14. Glantz, L. H., G. J. Annas, M. A. Grodin, and W. K. Mariner. 1998. "Research in Developing Countries: Taking 'Benefit' Seriously." *Hastings Center Report* 28 (6): 38–42.
15. Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, eds. 1996. *Cost Effectiveness in Health and Medicine*. New York: Oxford University Press.
16. Gruskin, S., and D. Tarantola. 2001. "Health and Human Rights." In *Oxford Textbook on Public Health*, ed. R. Detels and R. Beaglehole. Oxford, U.K.: Oxford University Press.
17. Hadorn, D. 1991. "Setting Health Care Priorities in Oregon." *Journal of the American Medical Association* 265 (17): 2218–25.
18. Holm, S. 1998. "Goodbye to the Simple Solutions: the Second Phase of Priority Setting in Health Care." *British Medical Journal* 317: 1000–7.
19. Horsman, J., W. Furlong, D. Feeny, and G. Torrance. 2003. "The Health Utilities Index (HUI®): Concepts, Measurement Properties, and Applications." *Health and Quality of Life Outcomes* 1 (1): 54.
20. Kamm, F. M. 1993. *Morality/Mortality. Volume One. Death and Whom to Save from It*. Oxford, U.K.: Oxford University Press.
21. Keeler, E. B., and S. Cretin. 1983. "Discounting of Life-Saving and Other Non-monetary Effects." *Management Science* 29 (3): 300–6.
22. Meltzer, D. 1997. "Accounting for Future Costs in Medical Cost Effectiveness Analysis." *Journal of Health Economics* 16 (1): 33–64.
23. Menzel, P., P. Dolan, J. Richardson, and J. A. Olsen. 2002. "The Role of Adaptation to Disability and Disease in Health State Valuation: A Preliminary Normative Analysis." *Social Science and Medicine* 55 (12): 2149–58.
24. Moss, A. H., and M. Siegler. 1991. "Should Alcoholics Compete Equally for Liver Transplantation?" *Journal of the American Medical Association* 265 (10): 1295–98.
25. Murray, C. J. L. 1994. "Quantifying the Burden of Disease: The Technical Basis for Disability-Adjusted Life Years." In *Global Comparative Assessments in the Health Sector: Disease Burden, Expenditures, and Intervention Packages*, ed. C. J. L. Murray and A. D. Lopez. Geneva: World Health Organization.
26. National Bioethics Advisory Commission. 2001. "When Research Is Concluded—Access to the Benefits of Research by Participants, Communities, and Countries." In *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*. Washington, DC: U.S. Government Printing Office.
27. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Office of the Secretary, U.S. Department of Health, Education, and Welfare. 1979. "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." U.S. Department of Health, Education, and Welfare, Washington, DC.
28. Nord, E. 1999. *Cost-Value Analysis in Health Care: Making Sense out of QALYs*. Cambridge, U.K.: Cambridge University Press.
29. Nord, E., J. Richardson, H. Kuhse, and P. Singer. 1996. "The Significance of Age and Duration of Effect in Social Evaluation of Health Care." *Health Care Analysis* 4 (2): 103–11.

30. Nord, E., J. Richardson, A. Street, H. Kuhse, and P. Singer. 1995. "Who Cares about Cost? Does Economic Analysis Impose or Reflect Social Values?" *Health Policy* 34 (2): 79–94.
31. Office of the Inspector General, U.S. Department of Health and Human Services. 1998. *Institutional Review Boards: A Time for Reform*. Washington, DC: U.S. Government Printing Office.
32. ———. 2000. *Protecting Human Subjects: Status of Recommendations*. Washington, DC: U.S. Government Printing Office.
33. Parfit, D. 1991. "Equality or Priority." Lindley Lecture. Department of Philosophy, University of Kansas, Lawrence, KS.
34. Rawls, J. 1971. *A Theory of Justice*. Cambridge, MA: Harvard University Press.
35. Rockefeller Commission (Commission on CIA Activities within the United States). 1975. *Report to the President*. Washington, DC: U.S. Government Printing Office.
36. Scanlon, T. M. 1997. *What We Owe to Each Other*. Cambridge, MA: Harvard University Press.
37. Solomon, J., and C. Murray. 2002. "A Conceptual Framework for Understanding Adaptation, Coping, and Adjustment in Health State Valuations." In *Summary Measures of Population Health*, ed. C. Murray, J. Salomon, C. Mathers, A. Lopez, and J. Lozano. Geneva: World Health Organization.
38. Weinstein, M., and W. B. Stason. 1997. "Foundations of Cost-Effectiveness Analysis for Health and Medical Practices." *New England Journal of Medicine* 296 (13): 716–21.
39. Wikler, D. 2002. "Personal and Social Responsibility for Health." *Ethics and International Affairs* 16 (2): 47–55.
40. Williams, A. 1997. "Intergenerational Equity: An Exploration of the 'Fair Innings' Argument." *Health Economics* 6 (2): 117–32.

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Useful Link

- Martin F. McKneally, Bernard M. Dickens, Eric M. Meslin, et al., "Bioethics for clinicians: 13. Resource allocation," *Canadian Medical Association Journal*, vol. 157, no. 2 (1997): 163-167. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1227741/pdf/cmaj_157_2_163.pdf.

3: Medical Error

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Cases for Discussion

- **Case 1**

An athlete requires arthroscopy of his right knee under general anesthesia. Just before finishing the procedure it is discovered that they were operating on the wrong (left) knee and the surgeon then proceeds to do the arthroscopy of the other (correct) knee. The surgeon explains to the patient after he wakes up, that as he is an athlete he also looked inside the other knee to make sure it was OK.

- What should you do as a resident who also assisted in surgery?
- Should someone be punished?
- Apart for the error itself what is wrong about the case?
- Should truth be told? And by whom?

- **Case 2**

A 40 year old abdominal gunshot wound victim is in the ICU (2nd day) after abdominal surgery which showed that mainly his stomach was damaged. He is incubated and ventilated but his prognosis is good and he should be able to make a full recovery. Because of the gunshot a portion of his stomach duodenum is removed. He is being fed through a line in his intestine.

A nurse on duty inadvertently attaches the intestinal feeding line to his intravenous line. This increases his heart rate, his blood pressure drops and he requires a short CPR. The wrong line insertion is noted and removed. Because of this mishap he will require a much longer stay in the ICU. The nurse is terrified and explains that she was only relieving another nurse and had limited experience in the ICU.

Discuss the ethical issues here.

What would be the ethical way of proceeding with this case?

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Teaching Video

To Err is Human: <https://vimeo.com/153865932>

To err is indeed human, and healthcare providers are as human as others. However, their errors have far greater significance as their acts of omission and commission can have an irremediable impact on those under their care. This video explores various aspects of medical mishaps while depicting incidents of error, negligence and near misses in the clinical setting. We hope that the video will generate an ethical discourse on why we err, and what to do when we do.

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<http://karachibioethicsgroup.org/PDFs/handbook-07-09-15.pdf>

Understanding Medical Error Karachi Bioethics Group

Preface

This handbook is an overview on medical error. It addresses concepts related to the subject and attempts to clear understanding of related terminologies. The text also highlights the importance of reporting, its analysis and how to disclose medical errors. In addition a legal opinion on Pakistani laws pertaining to the subject is also given. The readers will find this book of immense help in not only identifying medical error but also managing it.

The Karachi Bioethics Group (KBG), a voluntary group of healthcare related professionals, provides a common platform for discussion on bioethics issues. In December 2013, the group identified the need for a booklet on medical error. It was observed that there is a lack of understanding and dialogue on the subject. This was highlighted by the growing distrust of the society toward the healthcare professionals and ambiguity of media reporting on the events and incidents related to health care. For the purpose, a sub-committee was identified including Dr. Naima Zamir and Dr. Tayyaba Batool, pediatric surgeons at the National Institute of Child Health (NICH), Dr. Yasmin Wajahat, an obstetrician and gynecologist at Sindh Government Qatar Hospital, and two general surgeons Dr. Nida Wahid Bashir and Dr. Bushra Shirazi at Patel Hospital and Ziauddin Medical University respectively. Ms. Sharmeen Khan, an advocate, gave the legal opinion on Pakistani law.

Over the last one year the committee members met approximately 15 times reviewing the literature and jotting down various points on the subject. In this tenure of meetings an initial draft was made and shared with the Karachi Bioethics Group. Followed by several communications with the larger group and incorporating their comments, today in hand we hold the final product in print.

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Introduction:

Error must be accepted as evidence of system flaws, not character flaws.¹

Medical errors affect clinical practice and can occur with anyone involved in the medical profession. Understanding what constitutes medical error, its timely identification and judicious reporting is the mainstay of safe and ethical medical practice. This handbook is an initiative not only to guide and understand medical errors; its implementation will also help to improve the standard of care.

Every day, Pakistani media are reporting incidents of death or disability of patients without any discrimination between medical error, i.e. an unintentional act of omission or commission in the delivery of care, and medical negligence i.e. a failure to meet the standard of care. Concepts regarding the two are unclear not only to the media, but also to doctors, paramedics and all related personnel. In addition, in Pakistan, there is no definite mechanism or guideline that helps healthcare providers to analyze and deal with these events.

A report from Harvard School of Public Health referenced in the Times of India states that approximately 43 million people are injured from medical errors world over causing 23 million deaths.² The same article proceeds to say that two thirds of these cases occur in developing countries.

In the United States, medical error is the third leading cause of death after cancer and heart attack.³ In addition, we see literature quoting that approximately 2 to 4.5 million people face preventable medical harm.⁴ One of the studies suggests that 70% of adverse events results from medical error and are preventable.⁵ In European Union countries, like the United Kingdom, Spain and France the reported incidence of medical error are about 8% to 12% of hospitalization⁶, while Canada has 17% incidence of self reporting medical errors.⁷

Not all medical errors result in harm; therefore, many of them go unnoticed. It is of equal importance to identify these near misses to prevent possible adverse events.

A key concern associated with medical error is a financial burden as shown by reports from the United States, illustrating a total annual cost ranging from \$985 million in 2008 to over \$1 billion in 2009.⁸ This is a measurable impact of medical error. There are many immeasurable outcomes like death, disability, pain, and suffering of the patient and family. Furthermore, features like time away from work and home based medical investigation have not been taken into account in the available literature. Another major impact of medical errors is increasing public distrust in the medical system. In addition, healthcare providers also face moral discomfort and distress.

It is important to realize that the identification of medical error helps in bringing about policy changes in the system that prevent repetition of such events in the future. It should be understood that it is impossible to achieve risk free interactions between humans and machines so the aim should be to keep the incidence of error As Low as Reasonably Possible (ALARP).

DEFINITIONS

Before proceeding to error reporting guidelines, it is essential to have a clear concept of important terminologies and the differences between them.

Medical Error:

An act of omission or commission in planning or execution that contributes or could contribute to an unintended result.⁹ The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.¹⁰

Examples:

Reading 15 microgram medication as 15 milligram and giving the wrong dose.

Marking the wrong side of a reducible inguinal hernia for surgery.

Medical Negligence:

Medical negligence is a legal term and is defined here to differentiate it from medical error.

Failure to meet the standard of care reasonable expected of an average physician qualified to take care of the patient in question.⁹ In law medical negligence is determined as a three-part test establishing that the doctor owed a duty of care, it was breached, and as a direct result of breach the patient suffered a harm.¹¹

Examples:

Leaving a swab in the abdominal cavity during closure.

Uterine rupture, resulting from an attempt at vaginal delivery in a patient with previous three cesarean sections.

Malpractice:

Refers to an act of negligence by medical professionals which results in further deterioration in the patient's health and may eventually result in this death. At times, it may be related to misdiagnosis of particular disease. At other times it may be a case of criminal offence done on purpose for financial gains.¹²

Examples:

With a clear history of foreign body aspiration, choking and respiratory distress in a child, physician continues to treat the child with medical therapy instead of taking necessary steps for extraction of foreign body. Doing multiple root canals on a tooth that needs extraction.

Adverse Event:

An unintended injury to the patient caused by medical management rather than the underlying condition of the patient resulting in a measurable disability prolonged hospitalization, or both.⁹

Examples:

In a patient with pneumonia where the doctor gives an antibiotic to treat the patient and the patient has an anaphylactic reaction and the outcome is the need of ventilator support.

Rectal perforation caused during a barium enema in a child suspected with Hirschsprung's disease.

Near Miss:

Any event that could have had an adverse consequence for the patient, but did not, and was indistinguishable from a full-fledged adverse event in all but the outcome.⁹ In other words, a variation in health care delivery which did not affect the outcome, but for which did not affect the outcome, but for which a recurrence carries a significant chance of a serious outcome.¹³

Examples:

In a patient with pneumonia when the doctor prescribes a penicillin group antibiotic to treat the patient and the patient while purchasing the medicine from the pharmacy reveals that he is allergic to penicillin.

A doctor writes an illegible prescription that could lead to a harmful overdose, but an alert pharmacist identifies the danger and calls to double check the dose.

Complication:

Complications in medicine are defined as an unanticipated problem that arises following and can be the result of a procedure, treatment, or the illness. A complication is so named because it “complicates the situation”¹⁴.

Examples:

Seroma (fluid collection) formation following mastectomy.
Allergic reaction during blood transfusion.

WHY MEDICINE IS SUSCEPTIBLE TO ERROR

The practice of medicine is inherently interdependent at many levels and it is for this reason that the field of medicine is susceptible to errors. The causes of medical error are varied and include:

- System constraints
- Staffing problems
- Fatigue of health care provider
- Lack of knowledge
- Inadequate communication and continuity of care
- Lack of experience
- Complexity and urgency of care
- Improper documentation
- Illegible handwriting

AREAS SUSCEPTIBLE TO ERROR

It is usually presumed that the medical error is associated with the work done by doctors and nurses in the ward and clinical areas, but it is important to note that every support service associated with healthcare is susceptible to it. It includes the following:

- Clinical practice
- Nursing
- Pharmacy
- Hospital administration
- Laboratory
- Radiology
- Infection control
- Diet office
- Security (e.g. inadequacy of traffic control in clinical areas)

RELUCTANCE TO REPORT

Medical professionals hardly ever report their errors. There are multiple factors responsible for this reluctance including fear of losing one’s reputation, losing patient’s trust, and being labeled as incompetent. In our culture, blaming the individual rather than the system hinders reporting. It is also seen that there is a lack of understanding of terminologies ‘medical error’ and ‘negligence’. Finally, a pertinent reason for not reporting is that no mechanisms of reporting exist or it is considered cumbersome and stigmatizing.

Classification of Medical Error (According to Leap 1993)¹⁵

DIAGNOSTIC	Error delaying diagnosis
	Failure to employ indicated test
	Use of dated tests or therapy
	Failure to act on results of monitoring of testing
TREATMENT	Error in the performance of an operation, procedure or test
	Error in administering the treatment
	Error in the dose or method of using a drug
	Avoidable delay in treatment or in responding to an abnormal test
	Inappropriate care (not indicated)
PREVENTIVE	Failure to provide prophylactic treatment
	Inadequate monitoring or follow-up of treatment
OTHERS	Failure of communication
	Equipment failure
	Other system failure

REPORTING ERRORS

Importance of Reporting:

The reporting of an error is a fundamental step toward error prevention. Reporting those errors that result in patient harm, as well as trivial errors and near misses have the potential to strengthen processes of care and improve the quality of care in future patients. This effectively improves the health care system in the long run.

Ethics of Reporting:

Error reporting in medicine encompasses ethical concepts of professionalism, non-maleficence, patient advocacy and organization ethics edging towards obligation. Professionalism demands truth telling, auditing and learning from the practice. Therefore any time an error is committed or observed, steps should be taken to report, analyze and learn from it.

The Hippocratic Oath binds doctors to do no harm. Patient advocacy is a core concept of ethical medical practice and demands that a health care worker should report any error observed in clinical practice so that the harm can be prevented or corrected in that particular patient and in future patients.

All this is applicable to and becomes a responsibility of any organization involved in health care delivery. Any ethical organization is required to provide care with compassion. It is important to realize that any system of error reporting and analysis will be ineffective without the commitment of policy makers in the organization.

Essential of Error Reporting:

Reasons for inadequate error reporting include systems focusing on events that lead to grievous harm and reacting to it, fear of penalization of junior staff and naming and shaming. It is recommended that the following suggestions can help to address these concerns:

- Low threshold
 - Near misses and minor events should all be recorded

- Blame-free
 - Reporting error should be taken as a sign of professionalism and responsibility and not as a means to punish others
- Applied to all levels
 - Not just juniors
- Systematic analysis for system improvement¹⁶

Guidelines for reporting errors:

Error can be reported by a person who has observed it or was involved in it. Reporting policies may differ in different institutions and may be mandatory or voluntary. Before initiating a policy on medical error reporting, it is imperative for institutions to first create awareness about concepts related to the topic amongst all healthcare workers, followed by dissemination of information about the mechanism of reporting.

The first step is to initiate a reporting form. The person who observed the error or by whom the error occurred can fill this form. The form should be available at all times and placed in a neutral venue with drop box facility to submit it. At this point it is important to emphasize that every individual should feel secure in his job or reputation to be willing to fill the form. If this is not the case then reporting mechanisms will fail.

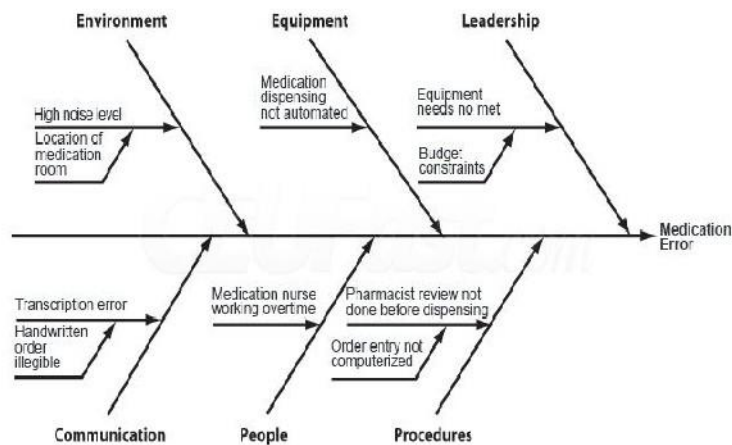
Error Analysis:

Analysis of reported medical errors is crucial to identify deficits in the system and suggest policy changes. This is accomplished by identifying the root cause for the occurrence of the error and suggesting corrective and preventive measures.

Root Cause Analysis:

It involves looking at what happened, why it happened, what has been learned and what changed.¹⁷ It includes gathering information, looking at different aspects of the problem, listing sequence of events, looking at contributing factors, identifying root cause and developing corrective action plans and follow-up plans.¹⁸

Various formats exist to conduct analysis of error including the framework provided by Joint Commission for International Accreditation (JCIA) and the fish bone framework given by WHO as shown below.¹⁹



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Error Analysis Team:

Formulation: The team can vary from institution to institution in its composition. It may comprise of a clinician, a pharmacist, a nurse, a member of quality assurance, a member of an ethics committee and a person from the administration.

Responsibilities: The responsibilities of the team include a detailed root cause analysis of the event through interviewing individuals involved, examination of the site and review of records, followed by suggested corrective and preventive measures. In addition to the above, the team should do a regular audit to look at the frequency and type of medical errors and re-evaluate the status of implementation of suggested policy changes.

Reporting Relationship: The team reports to the clinical head of the institute to ensure changes in policy.

Tools to Minimize Error:

- Check lists
- Digitalization of data and procedures
- Departmental audits
- Morbidity and mortality conferences since early 1900^{20,21,22}
- Performance standards
 - National and international licensing, certification and institution accreditation
 - Quality assurance programs
 - Patient safety practices and programs
- Disclosure policy

Disclosure:

Disclosure is a process of sharing information about medical error with the patient and/or patient's family. The underlying ethical principles include the right of the patient to know about facts related to his/her medical care and the duty of the care provider to give honest, full and timely information.²³ Disclosure involves acknowledgement of the error, providing its full details to the patient, possible outcome, remedy, ways to manage the complications (if they occur). Communication entails truth telling and openness and should be blame free. The central element of the error disclosure is the relationship of trust between physician and the patients.²⁴

Both the physician and the patient benefit from the disclosure of error. It decreases the distress and confusion in the physician and the patient²⁵ and also decreases the possibility of litigations.²⁶ In addition, it increases the chances of learning from errors (also the way it was managed), and the transmission of this information to others in order to prevent such errors in future.

The two main barriers to disclosure are, lack of communication skills in health care providers and the fear of loss of reputation.²⁷ Therefore, there should be a specific system of disclosure that can provide benefits to all the parties involved in a particular event. The systemic approach results in better understanding by the patients and improvement in the system of health care.²⁸ In an institute, the system should be taken as accountable and not the individuals.

Disclosure may be done by the primary physician, the person committing the error or by the institutional spokesperson. The disclosure should be in the patients' language in clear and simple words for them to understand and contribute to further management.

Disclosure is a continuing process and not a onetime discussion. The patient should be informed at every step of progress. An example of the disclosure process and the checklist is included in the booklet. Each individual of institution can modify these according to their circumstances and needs.

CHEKCLIST FOR DISLCOSURE PROCESS

- The immediate patient care needs to be met
- Ensure patient and staff's protection from harm
- Gather complete information and identify a focal person in the team who will be the representative communicator
- After compilation of information arrange meeting with the affectee or the family (Caution: be aware of emotional needs and support systems should be available)
- Explain in simple language the sequence of events and avoid any blame
- Apologize using the word "I am sorry" and invite family to ask any number of questions. Keep in mind the cultural needs
- Inform the family on the corrective measures taken²⁹

COMPENSATION IN MEDICAL ERRORS

Compensation can be a demand of the effected or the family but also a positive gesture on the part of the individual healthcare worker or organization. Disclosure and apology, waiving of fee by individuals and institutional mechanisms to deal with these cases are various ways of offering compensation.

An expectation or plea of the family is often that such an event never happens again. This can be achieved through reporting and analysis mechanisms.

An interesting and encouraging compensation system is the "no fault" system practiced in Denmark, Sweden, New Zealand and Finland where clinicians help the patient in compensation claim as a duty of care.

LEGAL IMPLEMENTATIONS IN PAKISTAN

In Pakistan, the legislation on medical negligence is not fully developed and in fact the frenzy created due to heightened awareness of medical negligence did not conclude in a separate standalone law on this area. So medical error, negligence and malpractice, through distinct terms in law are all redressed either within the criminal law space (Pakistan Penal Code which describes specific penalties based on the harm caused due to negligence as well as provides for *Diyat* for injury or death) or under the civil process where patients and families impacted by the medical error of a doctor may seek damages under the general laws of Torts by satisfying certain principles established under the common law (such as a duty existed for care that was breached and that caused the damage for which relief is sort. The laws dealing with this area are Specific Relief Act and the precedents established in Pakistan on civil redress.)

For establishing the wrong under either civil or criminal procedures, the chain of causation has to be established, showing that the harm that was caused was a direct result of the negligence. However, in both arenas of law it is the healthcare specialists (through expertise sort by the court in the shape of expert witnesses etc.) who provide information for the 'standard of care' that are deemed to be required. In any case through the Pakistan Medical and Dental Council (and the rules that it crafted) there is a level of self-regulation too that is practiced and this means that the PMDC has a right to debar a doctor under the rules for negligence (but it has not defined the terms either.)

As a note of clarity, the Penal code has not criminalized medical negligence specifically but it has categorized all harms in specific areas of injury and death, grievous bodily harm, manslaughter etc. In recent history, doctors in the case of Imanae Malik were charged with murder, manslaughter and aiding

and abetting criminal acts – so this is a way of prosecution. However, there is no specific law on medical negligence. This area needs more development in Pakistan because if you ask who benefits more by lack of legislation in this area, the answer would be that neither the healthcare community nor the patients are beneficiaries where such wide discretionary powers are provided to the judiciary or member of the PMDC. In fact, Pakistan needs well-drafted legislation in the area of medical laws.

CONCLUSION

This booklet offers readers introductory knowledge regarding medical error and a realization of the enormity of the issue. We hope it will help people to initiate protocols on reporting medical errors, and form committees to manage events appropriately. Disclosure, employee security, good clinical practice and an appropriate standard in health care will also help in rebuilding doctor-patient trust.

In the end, we recommend that:

The process of minimizing errors must be taken as a responsibility of every individual involved in the health care system.

Medical error reporting systems must be incorporated in hospital policy. All healthcare providers should be trained in the process of quality care, safety and understand the value of a good outcome. It may lead to safe practice, a practice which abides by the standards of care because of better understanding, rather than by fear of legislation.

References

1. Toft B, Masie-Taylor H. Involuntary automaticity: a work-system induced risk to safe health care. *Health Services Management Research* 2005; 18: 211-6.
2. India records 5.2 million medical injuries a year’ – The Times of India. <http://timesofindia.indiatimes.com/india/India-records-5-2-million-medical-injuries-a-year/articleshow/22832260.cms>.
3. Davey S, Davey A. Medical errors in practice which medical fraternity must not forget: A critical look. *Int J Health Syst Disaster Manage* 2013; 1:190-3.
4. James, John T. A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care. *Journal of Patient Safety*. 2013; 9(3): 122-8.
5. Medical Errors: The Scope of the Problem. Fact sheet, Publication No. AHRQ 00-P037. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/qual/errba>.
6. <http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/data-and-statistics>.
7. O’Hagan J, MacKinnon NJ, Persaud D, Etchegary H. Self-reported medical errors in seven countries: implications for Canada: *Healthc Q*. 2009; 12: 55-61.
8. David GI, Gunnarsson CL, Waters HC, Horblyuk R, Kaplan HS. Economic measurement of medical errors using a hospital claims database. *Value Health*. 2013 Mar-Apr; 16 (2): 305-10.
9. Grober E. D, Bohnen J.M.A. Defining medical error. *Can J Surg*.2005; 48(1): 39-44.
10. Oyeboode F, Clinical error and medical negligence: *Advances of Psychiatric treatment*. 2006; 12: 221-7.
11. Bryden D, Storey I “Duty of care and medical negligence” *Advance Access publication* 19 June, 2011 pg 124-127.
12. www.buzzle.com/article/medical-malpractice-statute-of-limitation.html “Medical practices statute of limitations.”
13. http://medicalteamworkconsultants.com/articles/improved_patient_safety.pdf.
14. Medicinenet.com (www.medterms.com/script/main/art.asp?articlekey=25405) May 25 2014.
15. <http://www.intechopen.com/download/pdf/33272> 23 Mar 2012, A Challenge for Quality Assurance in the Greek Health System. Athanassios Vozikis and Marina Riga. University of Piraeus, Athens. Greece.
16. Piet Leroy “Medical errors: the importance of the bullet’s blunt end”. *Arch Srug*. 2010 Oct; 145(10):978-84.
17. <http://www.patient.co.uk/docor/significant-event-audit>.

18. <http://www.rcecs.com/MyCE/PDFDocs/course/V7123.pdf> .
19. http://www.jointcommission.org/Framework_for_Conducting_a_Root_Cause_Analysis_and_Action_Plan/
20. The Morbidity and Mortality Conference: The Delicate Nature of Learning from Error, Jay D. Orlander, MD, MPH, Thomas W. Barber, MD, and B. Graeme Fincke, MD Acad. Med. 2002;77:1001-6.
21. Prince JM, Vallabhaneni R, Zenati MS, Hughes SJ, Harbrecht BG, Lee KK, Watson AR, Peitzman AB, Billiar TR, Brown MT. Increased interactive format for Morbidity & Mortality conference improves education value and enhances confidence. J Surg Educ. 2007; 64(5):266-72.
22. Vincent Liu. Error in Medicine: The Role of the Morbidity and Mortality Conference. Virtual Mentor. 2005; 7(4).
23. <http://www.amednews.com/article/20110912/profession/309129949/5/Medicalerrorcallsforhonest-disclosure-amednews.com>.
24. Wolf ZR,. Hughes RG. Error reporting and disclosure. Chapter 35. Patient Safety and Quality: An Evidence-Based Handbook for Nurses.
25. Koch S, Weiss PM, Medical errors: Disclosure and apology: Contemporary OB/GYN., 2012; June.
26. Mazor KM, Reed GW, Yood RA, Fischer MA, Bari JI, and Gurwitz JH. Disclosure of Medical Errors: What Factors Influence How Patients Respond? J Gen Intern Med. Jul 2006; 21(7): 704-710.
27. Disclosure of Medical Errors - ACEP <http://www.acep.org/Clinical---Practice-Management/Disclosure-of-Medical-Errors/>.
28. Liang B A. A system of medical error disclosure: Qual Saf Health Care 2002; 11:64-68.
29. Canadian Disclosure Guidelines – http://www.chirofed.ca/english/pdf/CPSI_Canadian_Disclosure_Guidelines_EN.pdf.
30. Davis P, Lay-ye R. Fitzjohn, Hider P, Schuq S “Compensation of medical injury in New Zealand: does “no fault” increase the level of claim making and reduce social clinical selectivity?” J Health Polit Policy Law. 2002; 27(5); 833-54.

Appendix

Appendix 1:

Medical Error Reporting Form

1. Identification details
 - a. Name of the unit where error occurred : _____
 - b. Date of error : _____
 - c. Time of error : _____ am/pm
 2. Patient related details (if involved or affected by the error)
 - a. Name of the patient : _____
 - b. M.R. # of the patient : _____
 3. Services involved (more than one boxes can be tick marked)
 - a. Clinical / Medical
 - b. Nursing
 - c. Diagnostic
 - i. Laboratory
 - ii. Radiology
 - d. Blood bank
 - e. Support services
 - i. Infection control
 - ii. Pharmacy
 - iii. Food services department
 - iv. House keeping
 - v. Physiotherapy
 - vi. Stores
 - vii. Finance
 - viii. Human resource
 - f. Others (Describe): _____
 4. Description of event (if needed):

- Signature and contact number of reporting person (optional) : _____

Appendix 2:

Error analysis form

(For the use of error reporting and analysis team)

1. Date of analysis: _____
2. Error analysis details
 - a. Root cause (look at the attached form)
 - b. Type of error
 - i. Medication error
 1. Prescription
 2. Dispensing / preparation
 3. Dose
 4. Route of administration
 5. Timing of administration
 6. Error in communication
 - ii. Nursing care error (other than medication)
 - iii. Error in medical / clinical care
 1. Error in diagnosis
 2. Delay in diagnosis
 3. Error in management
 4. Error in judgment
 5. Delay in management
 6. Error in technique
 7. Error in communication
 - iv. Error in diagnostic services
 1. Delay in provision
 2. Error in testing
 3. Error in technique
 - v. Blood bank related errors
 1. Lack of provision
 2. Delay in provision
 3. Error in provision
 4. Error in technique
 - vi. Support service related errors
 1. Lack of provision
 2. Delay in provision
 3. Error in provision
 4. Error in technique
 - c. Suggested corrective measures:

d. Suggested preventive measures:

e. Lessons learnt:

f. Name and designation of authorities to whom these suggested measure were forwarded:

g. Follow up

i. Status of suggested measures at six months from the date of analysis:

ii. Status at one year:

iii. Further measures taken:

Appendix 3:

WHO guideline for surgical procedure safety

SURGICAL SAFETY CHECKLIST ¹

BEFORE INDUCTION OF ANAESTHESIA



BEFORE SKIN INCISION



BEFORE PATIENT LEAVES OPERATING ROOM

SIGN IN

TIME OUT

SIGN OUT

PATIENT HAS CONFIRMED <ul style="list-style-type: none"> ○ IDENTITY ○ SITE PROCEDURE ○ CONSENT 	CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE	Nurse Verbally Confirms with the Team: <ul style="list-style-type: none"> ○ The name of the procedure recorded ○ That instrument, sponge and needle counts are correct (OR not applicable). ○ How the specimen is labeled (including patient name) ○ Whether there are any equipment problems to be addressed.
Site marked/Not applicable	Surgeon, anesthesia professional and nurse verbally confirm <ul style="list-style-type: none"> ○ Patient ○ Site ○ Procedure 	
Anesthesia Safety Check Completed	ANTICIPATED CRITICAL EVENT <ul style="list-style-type: none"> ○ Surgeon reviews: What are the critical OR unexpected steps, operative duration, anticipated blood loss? ○ Anesthesia team reviews: Are there any patient specific concerns? ○ Nursing team reviews: Has sterility (including indicator results) been confirmed? Are there equipment issues Or any concerns? 	Surgeon, Anesthesia professional and nurse review the key concerns for recovery and management of this patient.
Pulse Oximeter on Patient and Functioning	Has Antibiotic Prophylaxis been given within the last 60 minutes?	
Does Patient Have A:		Yes Not applicable

<p>Known allergy? No Yes</p> <p>Difficult Airway/Aspiration on risk? 1. No 2. Yes, and equipment / assistance available?</p> <p>Risk of >500ml Blood loss (7 ml/kg in children)? No Yes, and adequate intravenous access and fluids planned</p>	<p>Is essential imaging displayed? Yes Not applicable</p>	
---	---	--

Appendix 4:²

Medications Errors Prevention Guidelines

The following suggestions can help to minimize errors in communication of drug orders:

Storage of Medications

- Use both generic names and brand names of drugs and store them in accordance to the disease, not in alphabetic order.

Writing of Prescriptions

A prescription should include:

- Date, drug name in block letter, strength in metric system (example: milligrams or grams)
- Frequency of full words, (for example four times a day, twice a day), route of administration
- Leading zero if a number is less than one (0.1), avoiding a trailing zero after a decimal (5.0)
- Signature and professional designation of authorized prescriber
- PRN/SOS orders should indicate a specific time interval
- All known patient allergies in admission and transfer order. The designation “no known allergies” should be used as appropriate
- An existing order may not be corrected, altered, added to, or modified in any way
- If change is necessary, the order must be discontinued and a new order written by the authorized prescriber
- When discontinuing a medication, the prescriber should write the name of the drug being discontinued
- Verbal medication orders should be discouraged unless there is no other alternative available

Medication Administration/Documentation

- Check the time, dose, and route of packaged medication against that transcribed on the institution/facility document and check the patient allergy
- Check the patient name band to verify patient identity
- Document medication administered on the appropriate documentation tool and any adverse reaction noted
- All corrections and late entries should be clearly marked as such
- Do not erase, obliterate, or attempt to edit notes previously written
- Indicate errors by drawing a single line through the error, writing the word “error” above the error, and initialing the error
- Late entries, entries made out of time sequence, or addenda should be clearly marked as such in the record, and properly dated, time and signed
- Explanation of any omitted doses

Appendix 4:³

For diagnosis error

- Obtain your own complete medical history
- Perform a focused and purposeful physical examination
- Generate initial hypotheses and differentiate those with additional history, physical exam, and diagnostic tests
- Pause to reflect-take a diagnostic “time out”
- Was I comprehensive?
- Did I consider the inherent flaws of heuristic thinking?
- Was my judgment affected by any other bias?
- Do I need to make the diagnosis now, or can I wait?
- What is the worst-case scenario?
- Embark on a plan, but acknowledge uncertainty and ensure a pathway for follow-up

References of international recommendations

1. WHO Guidelines for Safe Surgery 2009 Safe Surgery Saves Lives.
2. Quality Improvement Academic Medicine, Vol. 86, No. 3 / March 2011 3.
3. A physician Checklist for Diagnosis – Pennsylvania Patient Safety. Sep 2010.
<http://patientsafetyauthority.org/EducationalTools/PatientSafety/Tools/diagnosis/Documents/c.>

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Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, Eds, "To err is human: building a safer health system," *National Academies Press* (2000).

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To ERR is Human: Building a Safer Health System

Health care in the United States is not as safe as it should be and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies. Even using the lower estimate, preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS.

Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Among the problems that commonly occur during the course of providing health care are adverse drug events and improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities. High error rates with serious consequences are most likely to occur in intensive care units, operating rooms, and emergency departments.

Beyond their cost in human lives, preventable medical errors exact other significant tolls. They have been

Types of Errors	
Diagnostic	Error or delay in diagnosis Failure to employ indicated tests Use of outmoded tests or therapy Failure to act on results of monitoring or testing
Treatment	Error in the performance of an operation, procedure, or test Error in administering the treatment Error in the dose or method of using a drug Avoidable delay in treatment or in responding to an abnormal test Inappropriate (not indicated) care
Preventive	Failure to provide prophylactic treatment Inadequate monitoring or follow-up of treatment
Other	Failure of communication Equipment failure Other system failure
SOURCE: Leape, Lucian; Lawthers, Ann G.; Brennan, Troyen A., et al. Preventing Medical Injury. <i>Qual Rev Bull.</i> 19(5):144-149, 1993.	

estimated to result in total costs (including the expense of additional care necessitated by the errors, lost income and household productivity, and disability) of between \$17 billion and \$29 billion per year in hospitals nationwide. Errors also are costly in terms of loss of trust in the health care system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a long hospital stay or

disability as a result of errors pay with physical and psychological discomfort. Health professionals pay with loss of morale and frustration at not being able to provide the best care possible. Society bears the cost of errors as well, in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

A variety of factors have contributed to the nation's epidemic of medical errors. One of cited problem arises from the decentralized and fragmented nature of the health care delivery system or "nonsystem," to some observers. When patients see multiple providers in different settings, none of whom has access to complete information, it becomes easier for things to go wrong. In addition, the processes by which health professionals are licensed and accredited have focused only limited attention on the prevention of medical errors, and even these minimal efforts have confronted resistance from some health care organizations and providers. Many providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors. Exacerbating these problems, most third-party purchasers of health care provide little financial incentive for health care organizations and providers to improve safety and quality.

Health Care System at Odds with Itself

The Quality of Health Care in America Committee of the Institute of Medicine (IOM) concluded that it is not acceptable for patients to be harmed by the health care system that is supposed to offer healing and comfort a system that promises, "First, do no harm." Helping to remedy this problem is the goal of *To Err is Human: Building a Safer Health System*, the IOM Committee's first report.

In this report, issued in September 1999, the committee lays out a comprehensive strategy by which government, health care providers, industry, and consumers can reduce preventable medical errors. Concluding that the know-how already exists to prevent many of these mistakes, the report sets as a minimum goal a 50 percent reduction in errors over the next five years. In its recommendations for reaching this goal, the committee strikes a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations.

One of the report's main conclusions is that the majority of medical errors do not result from individual recklessness or the actions of a particular group this is not a "bad apple" problem. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. For example, stocking patient-care units in hospitals with certain full-strength drugs, even though they are toxic unless diluted, has resulted in deadly mistakes.

Thus, mistakes can best be prevented by designing the health system at all levels to make it safer to make it harder for people to do something wrong and easier for them to do it right. Of course, this does not mean that individuals can be careless. People still must be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Strategy for Improvement

To achieve a better safety record, the report recommends a four-tiered approach:

- **Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety.**

Health care is a decade or more behind many other high-risk industries in its attention to ensuring basic safety. This is due, in part, to the lack of a single designated government agency devoted to improving and monitoring safety throughout the health care delivery system. Therefore, Congress should create a Center for Patient Safety that would set national safety goals and track progress in meeting them; develop a research agenda; define prototype safety systems; develop, disseminate, and evaluate tools for

identifying and analyzing errors; develop methods for educating consumers about patient safety; and recommend additional improvements as needed.

Funding for the center should be adequate and secure, starting with \$30 million to \$35 million per year and growing over time to at least \$100 million annually modest investments relative to the consequences of errors and to the resources devoted to other public safety issues. The center should be housed within the Agency for Healthcare Research and Quality (AHRQ), which already is involved in a broad range of quality and safety issues, and has established the infra-structure and experience to fund research, education, and coordinating activities.

- **Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems.**

Under the mandatory reporting system, state governments will be required to collect standardized information about adverse medical events that result in death and serious harm. Hospitals should be required to begin reporting first, and eventually reporting should be required by all health care organizations. This system will ensure a response to specific reports of serious injury, hold health care organizations and providers accountable for maintaining safety, provide incentives to organizations to implement internal safety systems that reduce the likelihood of errors occurring, and respond to the public's right to know about patient safety. Currently, about a third of the states have mandatory reporting requirements.

Voluntary reporting systems will provide an important complement to the mandatory system. Such systems can focus on a much broader set of errors, mainly those that do no or minimal harm, and help detect system weaknesses that can be fixed before the occurrence of serious harm, thereby providing rich information to health care organizations in support of their quality improvement efforts. To foster participation in voluntary systems, Congress should enact laws to protect the confidentiality of certain information collected. Without such legislation, health care organizations and providers may be discouraged from participating in voluntary reporting systems out of worry that the information they provide might ultimately be subpoenaed and used in lawsuits.

- **Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care.**

Setting and enforcing explicit performance standards for patient safety through regulatory and related mechanisms, such as licensing, certification, and accreditation, can define minimum performance levels for health professionals, the organizations in which they work, and the tools (drugs and devices) they use to care for patients. The process of developing and adopting standards also helps to form expectations for safety among providers and consumers.

Standards and expectations are not only set through regulations, however. The values and norms set by the health professions influence the practice, training, and education for providers. Thus, professional societies should become leaders in encouraging and demanding improvements in patient safety, by such actions as setting their own performance standards, convening and communicating with members about safety, incorporating attention to patient safety in training programs, and collaborating across disciplines.

The actions of large purchasers of health care and health care insurance, as well as actions by individual consumers, also can affect the behaviors of health care organizations. Public and private purchasers, such as businesses buying insurance for their employees, must make safety a prime concern in their contracting decisions. Doing so will create financial incentives for health care organizations and providers to make needed changes to ensure patient safety.

- **Implementing safety systems in health care organizations to ensure safe practices at the delivery level.**

Health care organizations must develop a “culture of safety” such that their workforce and processes are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal that is demonstrated by strong leadership on the part of clinicians, executives, and governing bodies. This will mean incorporating a variety of well-understood safety principles, such as designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and enabling care providers to avoid reliance on memory. Systems for continuously monitoring patient safety also must be created and adequately funded.

The medication process provides an example where implementing better systems will yield better human performance. Medication errors now occur frequently in hospitals, yet many hospitals are not making use of known systems for improving safety, such as automated medication order entry systems, nor are they actively exploring new safety systems. Patients themselves also could provide a major safety check in most hospitals, clinics, and practice. They should know which medications they are taking, their appearance, and their side effects, and they should notify their doctors of medication discrepancies and the occurrence of side effects.

Progress Under Way

The response to the IOM report was swift and positive, within both government and the private sector. Almost immediately, the Clinton administration issued an executive order instructing government agencies that conduct or oversee health-care programs to implement proven techniques for reducing medical errors, and creating a task force to find new strategies for reducing errors. Congress soon launched a series of hearings on patient safety, and in December 2000 it appropriated \$50 million to the Agency for Healthcare Research and Quality to support a variety of efforts targeted at reducing medical errors.

The AHRQ already has made major progress in developing and implementing an action plan. Efforts under way include:

- Developing and testing new technologies to reduce medical errors
- Conducting large-scale demonstration projects to test safety interventions and error-reporting strategies
- Supporting new and established multidisciplinary teams of researchers and health-care facilities and organizations, located in geographically diverse locations that will further determine the causes of medical errors and develop new knowledge that will aid the work of the demonstration projects
- Supporting projects aimed at achieving a better understanding of how the environment in which care is provided affects the ability of providers to improve safety
- Funding researchers and organizations to develop, demonstrate, and evaluate new approaches to improving provider education in order to reduce errors

Casting its net even more broadly, the AHRQ has produced a booklet of practical tips on what individual consumers can do to improve the quality of health-care services they receive. The booklet focuses on key choices that individuals and their families face, such as choosing doctors, hospitals, and treatments, and it stresses the importance of individuals taking an active role in selecting and evaluating their care. (The booklet is available on the organization’s Web site at www.ahrq.gov).

In efforts focused at the state level, during the past year the National Academy for State Health Policy (NASHP) convened leaders from both the executive and legislative branches of the states to discuss approaches to improving patient safety. The NASHP also helped lead an initiative to better understand

how states with mandatory hospital error-reporting requirements administer and enforce their programs. (A report on this initiative is available on the organization's Web site at www.nashp.org). In addition, the Agency for Healthcare Research and Quality has contracted with the National Quality Forum to produce a list of so-called "never events" that states might use as the basis of a mandatory reporting system.

Among activities in the private sector, the Leapfrog Group, an association of private and public sector group purchasers, unveiled a market-based strategy to improve safety and quality, including encouraging the use of computerized physician-order entry, evidence-based hospital referrals, and the use of ICUs staffed by physicians credentialed in critical care medicine.

Professional groups within the health-care community also have been active. As but one example, the Council on Graduate Medical Education (COGME) and the National Advisory Council on Nurse Education and Practice (NACNEP) held a joint meeting on "Collaborative Education Models to Ensure Patient Safety." Participants addressed such issues as the effect of the relationships between physicians and nurses on patient safety, the impact of physician-nurse collaboration on systems designed to protect patient safety, and educational programs to ensure interdisciplinary collaboration to further patient safety. (A report on the meeting is available on the COGME's Web site at).

Pulling Together

Although no single activity can offer a total solution for dealing with medical errors, the combination of activities proposed in *To Err is Human* offers a roadmap toward a safer health system. With adequate leadership, attention, and resources, improvements can be made. It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead.

For More Information

Copies of *To Err is Human: Building a Safer Health System* are available for sale from the National Academy Press; call (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area), or visit the NAP home page at www.nap.edu. The full text of this report is available at:

<http://www.nap.edu/books/0309068371/html/>

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Useful Links

- Rabbi Abraham J. Twerski, "Medical errors: Focusing more on what and why, less on who," *Journal of Oncology Practice*, vol. 3, no. 2 (March 2007): 66-70.
- Dr. S. P. Kalantri, "Medical errors and ethics," *Indian J. Anaesth*, vol. 47, no. 3 (2003): 174-175.
- David M. Studdert, Troyen A. Brennan, "No-Fault compensation for medical injuries: The prospect for error prevention," *The Journal of the American Medical Association*, vol. 286, no. 2 (2001): 217-223.
- Vicki D. Lachman, "Patient safety: The ethical imperative," *MEDSURG Nursing*, vol. 16, no. 6 (2007): 401-403.
- Bryan A. Liang, "A system of medical error disclosure," *Quality and Safety in Health Care*, vol. 11, no. 1 (2002): 64-68.
- "World Alliance for Patient Safety, WHO Draft Guidelines for adverse event reporting and learning systems, from information to action," Printed by the *WHO Document Production Services*, Geneva, Switzerland (2005).
- Florence Poillon ed., "To Err is Human: Building a Safer Health Care System," Institute of Medicine, *National Academy of Sciences* (1999): 1-8.
<http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf>.

4: Using Patients for Education and Training

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Case for Discussion

During a clinical rotation in your 3rd year, you have been taught a few basic principles of clinical examination which include taking informed consent and maintaining confidentiality.

You have a bedside teaching session with your batch and clinical teacher in the ward. Your teacher asks you to go ahead and do the physical examination. You ask for permission from the patient but the patient refuses. However, your teacher tells you to go ahead ignoring the patient's wishes.

Has your teacher behaved ethically?

What should you (the student) do?

What is your responsibility as a future physician?

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Saima P. Iqbal, "Patients' Perceptions on Their Involvement in Medical Education: A Qualitative Pilot Study," *Journal of Academic Ethics*, vol. 11, no. 4 (2013): 257-264.

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Patients' Perceptions on their Involvement in Medical Education: A Qualitative Pilot Study

Saima Perwaiz Iqbal

Abstract

Patients' perception with regards to their use in medical teaching is an under-researched area in Pakistan. The objective of this qualitative, pilot study was to determine the perspectives of hospital admitted patients on their being used in the medical education of students in a private medical institution. An attempt to understand the dynamics of interactions between patients, students and doctors was also made and to see how this affected the doctor-patient relationship. A qualitative study with in-depth interviews was conducted in a private medical college of Islamabad, Pakistan with a total of 20 adult patients. The focus was on their experiences with bedside teaching. This pilot study reveals interesting findings about patient-physician interactions in Pakistan. Patients had a traditionally passive role in medical education putting more onuses on the doctor to impart knowledge to the medical students. Patients comforted themselves in the knowledge that they were following Allah's command when they were involved in the teaching of medical students. The apparent altruism of Pakistani patients in this study was influenced mainly by religious reasons, following the commandments of Allah to help develop future healers for humanity. The culture evident in the medical college where this study was conducted is reflective of the social power ladders that pervade Pakistani society. The positions of doctors and medical teachers in Pakistani society are hardly challenged to debate. Little attention has been paid to the values that influence the cultural and social frameworks within which Pakistani medical teachers, medical students and the patients function.

Keywords Patients. Teaching. Medical Education. Ethics

This study was conducted a thesis requirement for a Masters in Bioethics from Sindh Institute of Medical Sciences. Ethics approval was taken from the Institutional Review Boards of Shifa College of Medicine, Islamabad, Pakistan and Sindh Institute of Medical Sciences, Karachi, Pakistan.

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Introduction

“He who studies medicine without books sails an unchartered sea, but he who studies medicine without patients does not go to sea at all”

Sir William Osler (1849–1919)

Patient contact in medical education is at the heart of learning which provides an opportunity for students and trainee doctors to learn and apply their knowledge and skills within existing settings. The educational benefits of patient contact are generally acknowledged to include motivation by emphasizing the significance of learning; development of clinical reasoning; appreciation of cultural diversity, and fostering empathy along with the development of professional and communication skills (British Medical Association [BMA] 2008).

In the undergraduate medical curriculum, patient contact can occur as part of clinical observation, supervised practice, real case based teaching or learning encounters with real or simulated patients (BMA 2008). These encounters mostly take place in hospital wards, outpatient clinics and community based settings.

Although patients may not benefit directly from the involvement of medical students in their care, educating these future doctors is essential for society. This forms one of the most inherent ethical dilemmas that medical educators face. The issues of informed consent, privacy and confidentiality and respect for persons are those that trouble not only the educator but also the trainee (BMA 2008). There may also be a “conflict of interest” on behalf of the medical students who are more focused on learning about the “disease” rather than the patient’s “illness” (Shooner 1997).

The customary apprenticeship approach to training has depended critically upon patient contact. The role of the patient in medical education has been passive, with the patient acting as a teaching tool or interesting teaching “material” in a traditional paternalistic model (Spencer et al. 2000). There is now a paradigm shift reported in Western societies for example in the United Kingdom (UK), of the physician-patient relationship between the teaching doctors and the more empowered patient. With the increased awareness of patients’ rights and informed consent, patients can now choose whether or not they wish to have medical students present in their consultation and care (Choudhury et al. 2006). The literature, from Western societies for example, the UK, USA, and Canada provides evidence to the fact that generally patients are favorable towards medical students’ presence in their consultations and that patients show a greater level of satisfaction when involved in medical education. Work published by Choudhury et al. (2006), Sousa et al. (2009), Mavis et al. (2006), Walters et al. (2003), Westberg et al. (2001), Coleman and Murray (2001) and Stacy and Spencer (1999) demonstrate this.

The advantages that patients see in their participation in medical students training include reception of better care and a more thorough consultation (Sousa et al. 2009). Patients also visualize themselves in a more active and expert role and perceive their contribution as being valuable for the greater good (Stacy and Spencer 1999). The reasons reported for their altruism are providing a service to the community and giving back to the health care system (Coleman and Murray 2001).

Literature regarding patients’ perceptions on being involved in teaching of medical students in the Eastern part of the world is almost non-existent. Limited data is available in Pakistan on how Pakistani patients perceive their involvement in medical education when being “used as teaching tools.” Mahmud and Ahmad (2010) have reported that patients in their study, carried out in Pakistan were willing to be seen by medical students after informed consent. The determination of the factors which influence patients’ perceptions on their involvement in medical education and how they differ from perceptions in the West was the prime objective of this study.

Methods

The General Medical Ward of a private medical college and hospital in a major city of Pakistan has been established to meet with the demands of medical teaching at the under-graduate and postgraduate level. Within this ward, there is a provision of quality services and medications at lower rates as compared to those who cannot afford the semi-private and private rooms offered by the attached hospital. It is occupied usually by patients belonging to the middle, lower middle and lower socioeconomic class of residents of the city and the surrounding suburban areas.

The General Medical Ward is a 40 bed facility and admits both adult male and female patients. The students of the fourth and final years visit the facility for at least 10 months during their Medicine rotations. There are daily teaching rounds of fourth and final year students within this ward.

A total of 20 adult patients, 10 male and 10 female were interviewed between the months of March-June 2011 with the focus being on their experiences with bedside teaching with the doctors and students while being admitted in hospital. This study was a thesis requirement for the Principal Investigator (PI) who was enrolled in a Masters in Bioethics program. The PI is a faculty member of the institution where this study was conducted and this was her first attempt at doing qualitative research with in-depth interviews. Keeping in mind, time constraints of the PI to conduct the interviews it was pre-decided to conduct an equal number of interviews in both genders. After gathering data of 14 patients (7 men and 7 women) we realized that similar themes were emerging. A further six interviews were conducted in the allotted time frame for data collection.

After receiving Institutional Review Board (IRB) approval and with permission of the Section Head of Internal Medicine the PI would go to the General Medical Ward for interviewing patients. The PI would approach the beds occupied by the patients and take an informed consent. All those patients who gave consent were interviewed. The PI would alternatively go to the male wing and female wing of the General Medical Ward.

An interview guide was developed prior to the study. It consisted of both closed ended and open ended questions gleaning information about demographics, the patients' understanding of their utility in medical education, what they gained from the clinical encounter with medical students present, their perceived role as facilitators and any problems or concerns they had. Questions explored the patients' perceptions on how the teaching affected the patient's relationship with their doctor and whether or not they would like to be involved in medical teaching in future. The questions were translated in the local language Urdu and available to the Principal Investigator (PI) prior to the interview. The questionnaire and interview guide is attached as Annexure 1 and 2 respectively.

All interviews were conducted by the PI. The interviews were audio taped after taking informed consent. If a patient refused audio taping then extensive hand written field notes by the PI were used. Interviews generally lasted from 45 min to an hour. Transcripts of the interviews were generated immediately afterwards.

The PI read and re-read the transcripts and field notes. The PI also shared these notes with her supervisor. The common and recurring themes which emerged from the transcripts and field notes were identified and scrutinized through constant comparative analysis (Glaser and Strauss 1967).

Results

A summary of demographic details of the patients is presented in Table 1. The names of the patients have been changed to protect their privacy.

From the conversations with the patients several consistent themes emerged. These are presented below and later on will be discussed in detail in the discussions section.

Language and the Patient's Role in the Teaching Round

During the interviews the patients described how the system of teaching medical students worked in the Ward. First the medical student would approach the patient on his or her allotted bed and ask for permission to interview and conduct a physical examination. Often there would be two or three students of the same batch approaching the patient at the same time. They would collectively interview and examine the patient. This interaction between student and patient would be in the local language Urdu. Most patients mentioned how students would ask the same questions several times or ask too many questions for that matter and would voraciously write each and every detail. This habit, particular to the students would cue the patients as to the importance of the task at hand in the eyes of the medical student. Then the teacher or facilitator who was usually a senior doctor or professor would arrive and conduct a teaching session by the patient's bedside. The student would present the history and findings of the examination in English and the discussion from there on between facilitator and student would be in English. During this time the patient is a silent observer who may or may not be following the discussion that takes place. If the patient needs to be addressed for more information by the student or teacher it would be in Urdu. This lack of involvement during the "intensive" teaching phase did not seem to bother any of the patients that were interviewed. They realized that the senior doctor was fulfilling his obligation to teach. At the end of the teaching round the patients were addressed by the senior doctor for issues relating to their management and care.

Table 1 Patient details (Names have been changed)

S. No	Patient ID	Sex	Age	Marital Status	Occupation	Education	Days spent in hospital prior to interview
1	Naima	F	31	Married	Housewife	Bachelors	1
2	Hidayat	M	82	Widower	Retired army officer	Middle (7th grade)	2
3	Masood	M	60	Married	Businessman	Illiterate	2
4	Younus	M	47	Married	Welder	Illiterate	3
5	Asif	M	64	Married	Retired army officer	Illiterate	9
6	Salman	M	50	Married	Businessman	Illiterate	3
7	Rashida	F	60	Married	Housewife	Illiterate	2
8	Maham	F	18	Unmarried	Student	1st year pre-engineering	13
9	Sanjeeda	F	32	Married	Housewife	Middle (8th grade)	3
10	Jan Mohammad	M	62	Married	Businessman	Middle (5th grade)	30
11	Sameera	F	58	Married	Housewife	Illiterate	3
12	Javed	M	54	Married	Businessman	Middle (8th grade)	14
13	Zafarullah	M	64	Married	Businessman	Matriculate	4
14	Liaquat	M	60	Married	Businessman	Intermediate	3
15	Khalid	M	46	Married	Driver	Middle (5th grade)	5
16	Farhat	F	48	Married	Housewife	Middle (5th grade)	2
17	Zarina	F	53	Widow	Housewife	Middle (5th grade)	2
18	Zubaida	F	34	Married	Housewife	Bachelors	3
19	Nadia	F	62	Married	Housewife	Illiterate	2
20	Sumbul	F	44	Married	Housewife	Illiterate	1

The “Majboor” Student

On being asked, how patients felt about the presence of medical students in their care, most patients interviewed felt compassion for the students because they saw them as “majboor.” The word “majboor” is an Urdu term which means “helpless”, or “without any choice.” Patients’ comments are shown in Table 2.

The issue of students being perceived as “majboor” was an intriguing finding and one not found as applied to medical students in Western literature. Pakistan exists as a hierarchical society and it was interesting to note that patients actually empathized with the students on perception of “shared majboori,” with the patients in front of disease and doctors, and students in front of their teachers. During conversations with the patients several of them talked about themselves being “majboor.” When probed as to what made them so, they answered that they were helpless or “majboor” because of their illness and because their recovery was dependent upon the medical care provided by the doctors in hospital. The “majboor” student was not seen as an empowered figure by patients when compared to the doctors. This fits in with the hierarchical description of the teaching round mentioned previously.

The Family Paradigm

Almost all patients appeared to perceive students as extended members of a family, the elder patients referring to them as their “children” or “like their children” or “like sons and daughters.” Rather than using the standard Urdu term “talib alim/tulba” which when translated in English means “student/students”, the patients used the word “bachchay” which means “children.” Generally, spoken Urdu in Pakistan is interspersed with English terms so patients would also use the word “student(s)” in their conversations but equate it with the term “bachchay.” The use of the term “bachchay” for the medical students was consistent in most interviewed patients irrespective of their own ages. Rashida, a 60 year old lady and mother to 11 children actually appreciated the fact that students addressed her as “*ammaan ji*” (a respectful term in Urdu for mother/elder lady). She mentioned her own daughter being a nursing student and said “When I see these children approaching my bed I am reminded of my own daughter who is a nursing student studying at a nursing college in another city.”

Masood, a 60 year old gentleman commented that he would never refuse medical students from being involved in his care. “If the students are getting what they want from my cooperation then let it be. They are also like my children.”

The familial paradigm as expressed by the patients was not surprising as ethnographic research in Pakistan has shown similar findings (Moazam 2006). Relationships in Pakistani society extend beyond blood relatives to close friends who may also be referred to as behan (sister) or bhai (brother). Similarly, doctors or trusted health care professionals may be accepted into the family unit and termed as maa (mother), baap (father) or an older behan or bhai. The cultural pattern in Pakistan is such that people confide in and trust family members rather than strangers. Patients therefore feel more comfortable seeking therapy from someone they can perceive as a family member (Moazam 2006). Patients in this study therefore looked at the students as members of an extended family. That is why most patients referred to them as or like their children. The average age of our fourth and final year medical student was between the ages of 22–24 and as most of the patients were in their 50s and 60s this was understandable.

Table 2 Theme of the “*majboor*” or “helpless” student

“It is the duty or obligation of the students to study” (Patient 3, 4, 5, 12, 17, 18, 19, 20)

“It is imperative upon them to learn, otherwise how will they treat patients in future?” (Patient 1, 2, 6, 7, 9, 10, 11, 12, 14, 16, 18, 19)

“I don’t like refusing students because they are also desperate. If we don’t co-operate, how will they learn?”(Patient 6, 12, 15)

Religion as an Important Factor

Patients were probed about how they felt and what were their thoughts once students and their teacher left the bedside. No one reported any negative feelings. When asked if they were given a choice to be involved in medical teaching or not patients said they would never refuse. When asked why, most of them replied that it would never occur to them to refuse because this was a good deed in the eyes of God. Some patients' comments about this theme are presented in Table 3.

The youngest of the patient participants was an 18 year old girl and she commented

“In our religion, (Islam) we are taught to be charitable and help those in need. If a beggar approaches our doorstep we do not refuse them and let them go empty-handed. So if students are in need for us (patients) to co-operate how can we refuse Allah's command?”

When patients were asked about their choice to be involved in medical education in future, all except one answered in the affirmative. When probed as to the reasons for this affirmation, they commented that it was in accordance to “Allah's will” due to the nobility of a doctor's profession and his work. Similar comments are shown in Table 3. Obviously, these patients saw the medical students as future physicians and healers although at present they may be “children.”

One patient remarked, “Allah expects this small sacrifice from us for the greater good of humanity and society.

Patients were asked if whether the type of illness that they had or sex of the students would influence their decision on involving students in their care. Most answered that this would not influence their decision. As one patient commented “Doctors are above such things.”

Table 3 Theme of religion

“Health is the hands of God or the doctor. The students cannot harm us” (Patient 1, 2, 3, 4, 6, 8, 9, 10, 11)

“Doctors can never be wrong. They do God's work.” (Patient 1, 2, 4, 5, 7, 12, 13, 14, 15, 16, 19, 20)

“If we become a hindrance in the learning process of students, God will not be happy with us.”(Patient 6, 8, 17)

“God helps them [students] because they do God's work.”

Discussion

This pilot study reveals interesting findings about patient-physician interactions in Pakistan that seem to differ from the norms represented in literature. The Western literature reports on the emerging active role of the patient in medical education rather than the more traditional passive role (Coleman and Murray 2001; Stacy and Spencer 1999). However, in this study patients that were interviewed appeared to take on a passive role and accepted this fact unquestionably. The onus was on the doctor or consultant to impart knowledge to the medical students. This is perhaps related to the fact that in Eastern cultures, social hierarchy is more prominent and generally accepted. A doctor is perceived to be of a higher social status, the status being defined in terms of education and money, and therefore he or she is obligated with greater responsibilities to benefit those people belonging to a lower social status (Claramita et al. 2011). The use of a different language for patients (i.e. Urdu) and students (i.e. English) also seemed to emphasize this hierarchy.

Patients also looked upon the medical students as or like their children. They also thought that the students were helpless and could empathize with them as they observed how the students persevered for approval from their clinical teachers. An element of parental affection for a helpless child or appreciation

of a student's predicament would influence the patient's cooperation on his or her involvement in medical education. This differs greatly from Coleman's (2001) study in the UK, where the patients' decisions on their participation in medical education were influenced primarily by altruism and personal gain. The altruism in Coleman's study was geared to providing service to the community and repaying the health system. Personal gain included an increase in knowledge about their medical condition and improved self esteem when contributing significantly to medical student education. The apparent altruism of Pakistani patients in this study was influenced by cultural (interaction between parent and child) and religious reasons such as following the commandments of Allah to help develop future healers for humanity.

With the increasing importance of "patient-centeredness" mostly in the United States and developed countries of Europe as mentioned by BMA (2008), Spencer et al. (2000), Coleman and Murray (2001) and Stacy and Spencer (1999), the applicability of this concept in Eastern countries like Pakistan has cultural, religious and practical nuances that warrant careful consideration. The doctor in Pakistan is considered to be an instrument of God (Allah) and therefore, held in high esteem by the society that respects authority and condones the hierarchal system (Moazam 2000). Therefore, the patients in this study believed themselves or maybe comforted themselves in the knowledge that they were following Allah's command when they were involved in the teaching of medical students, who will be doing God's work in future. The fact that these people were sick and admitted in hospital, vulnerable and dependent upon the doctors for treatment would likely influence their willingness on being involved in medical teaching. Also, Pakistani society is a collectivistic society, as opposed to the individualistic society of the West with greater emphasis on the family rather than the individual. Consent of the family is as important as consent of the individual. In majority of the patients that were interviewed, a family member was also present and actively participated in the discussions with the patients.

As this thesis was a qualitative pilot study, the findings cannot be generalized to represent a larger population. However a methodological attempt has been made to determine perceptions of patients, students and medical teachers with regards to the utility of patients in medical education. These findings are not unusual in the Pakistani context but this study needs to be expanded to include the perceptions of patients on being used for medical teaching among those who belong to a higher economic stratum and are paying more for health care services.

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Conflict of interest

No competing interests declared.

References

- (1) British Medical Association (2008). Medical Education Subcommittee September 2008 Role of the patient in medical education Available from URL: http://www.bma.org.uk/images/roleofthepatient_tcm27175953.pdf (Accessed 17th July 2011).
- (2) Choudhury, T. R., Moosa, A. A., Cushing, A., & Bestwick, J. (2006). Patients' attitudes towards the presence of medical students during consultations. *Medical Teacher*, 28(7), 198–203.
- (3) Claramita, M., Utarini, A., Soebono, H., Dalen, J. V., & Van der Vleuten, C. (2011). Doctor-patient communication in a Southeast Asian setting: the conflict between ideal and reality. *Advances in Health Sciences Education*, 16, 69–80.
- (4) Coleman, K., & Murray, E. (2001). Patients' views and feelings on the community based teaching of undergraduate medical students: a qualitative study. *Family Practice*, 19(2), 183–188.
- (5) Glaser, B. G., & Strauss, A. L. (1967). *The discovery of grounded theory*. Hawthorne: Aldine.

- (6) Mahmud, S. M., & Ahmad, A. (2010). Patients as teaching tools: merely informed or true consent. *Journal of Academic Ethics*. doi:10.1007/s10805-010-9099-7.
- (7) Mavis, B., Vasilenko, P., Schnuth, R., Marshall, J., & Jeffs, M. C. (2006). Medical students' involvement in outpatient clinical encounters: a survey of patients and their obstetricians-gynecologists. *Academic Medicine*, 81(3), 290–296.
- (8) Moazam, F. (2000). Families, patients and physicians in medical decision making: a Pakistani perspective. *The Hastings Center Report*, 30(6), 28–37.
- (9) Moazam, F. (2006). *Bioethics and organ transplantation in a Muslim society: a study in culture, ethnography and religion*. Bloomington: Indiana University Press.
- (10) Shooner, C. (1997). The ethics of learning from patients. *Canadian Medical Association Journal*, Feb 15, 1997; 156(4).
- (11) Sousa, A. C. J., Tajra, C. R. M., Coelho, R. S., Gomes, C. M., & Teixeira, R. A. (2009). Medical learning in a private hospital: patients' and companions' perspectives. *São Paulo Medical Journal*, 127(2), 101–104.
- (12) Spencer, J., Blackmore, D., Heard, S., McCrorie, P., McHaffie, D., Scherpbier, A., et al. (2000). Patient-oriented learning; a review of the role of the patient in the education of medical students. *Medical Education*, 34, 851–857.
- (13) Stacy, R., & Spencer, J. (1999). Patients as teachers: a qualitative study of patients' views on their role in a community-based undergraduate project. *Medical Education*, 33, 688–694.
- (14) Walters, K., Buszewicz, M., Russell, J., & Humphrey, C. (2003). Teaching as therapy: cross sectional and qualitative evaluation of patients' experiences of undergraduate psychiatry teaching in the community. *BMJ*, 326, 740.
- (15) Westberg, K., Lynoe, N., Lalos, A., Lofgren, M., & Sandlund, M. (2001). Getting informed consent from patients to take part in the clinical training of students: randomised trial of two strategies. *BMJ*, 323, 48.

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Caroline Shooner, "The ethics of learning from patients," *Canadian Medical Association Journal*, vol. 156, no. 4 (1997): 535-538.

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The Ethics of Learning from Patients

Caroline Shooner

In Brief

Is it Ethical for Medicine to Use Patients as learning tools for medical students if these patients have not been given a chance to provide truly informed consent? Dr. Caroline Shooner raises this question in the following article, which claimed second prize in CMAJ's 1996 Logie Medical Ethics Essay Contest. She considers the case of a patient whose trust was shaken when a medical student performed a chest-tube insertion. Shooner concludes that psychologic harm could have been avoided had the patient's right to informed consent been respected. She also argues that few patients will turn down a chance to help students learn if the request is made properly and openly.

During training, many of us have experienced the moral uneasiness that accompanies the process of learning clinical procedures by using real patients, often without obtaining their explicit and truly informed consent. Although such procedures are usually adequately supervised and unlikely to cause any physical harm, students are sometimes left with the uncomfortable feeling that somehow the relationship between physician and patient has been impoverished and violated. In the process of learning important skills that will benefit students and potentially benefit the patients they will eventually care for, the essential element of trust has been jeopardized. Clearly, the involvement of medical students in the assessment and care of patients may cause a potentially serious conflict between the trainee's need to learn and the patient's right to receive adequate care.¹⁻⁴ Although physicians-in-training need hands-on experience to master their craft, patients are entitled to the best and safest medical care available. In order to satisfy the need for adequate training while also respecting the principles of patient beneficence and autonomy, we must ensure that the principles of informed consent have been honoured. Often, this is not the case.⁵ We may find that, in the process of guaranteeing patients the right to decide what will be done to their bodies, we serve equally the ethics of patient care and the goals of teaching responsible, humane medicine.

Flustered Student, Worried Patient

To help understand essential elements of the potential conflict of interest between medical trainee and patient, consider this scenario.



Jane Smith (all names are fictitious), a third-year medical student, is starting the second week of an elective clinical rotation in cardiovascular thoracic surgery. The supervising resident has asked her to accompany him to see John Brown, a 65-year-old man with lymphoma who developed a pneumothorax after a left subclavian central line was inserted. The resident asks if Smith has inserted a chest tube before, and she says she hasn't but has witnessed the procedure twice in the past 2 weeks. This time, says the resident, she will perform the insertion. Eagerly, albeit somewhat anxiously, she accepts the offer.

As they enter Brown's room, the resident quickly introduces Smith as a "physician-in-training" and member of the surgical team, and adds that she will assist with the chest-tube insertion. Brown simply nods and utters "OK." No further explanation is requested or offered.

As the visitors prepare for the procedure, the patient notices that the "physician" holding the syringe containing the local anesthetic appears anxious. Sweat is forming on her forehead and she cannot hide a slight hand tremor. The resident calmly begins to explain the most important steps in a chest-tube insertion. At this point, Brown interrupts them by asking, "Has she ever done this before?"

Smith looks at the patient, then turns to the resident. A vague uneasiness fills the air, until the resident provides reassurance. "Don't worry Mr. Brown, Jane is familiar with this procedure. I myself have done it many times. We are going to perform it together. Everything will go fine."

The patient gives an unconvincing nod and turns on his right side as Smith and the resident begin to prep and drape him. Guided by the resident, Smith performs the insertion rather skilfully. The procedure completed, Brown turns to Smith and taps her on the arm. "You were pretty good, Doctor."

Smith smiles and offers Brown a moist handshake. The resident informs the patient that he will be sent for a chest x-ray after lunch, to ensure that the chest tube is well inserted, and then leaves the room, swiftly followed by the student.

Many medical students have shared Smith's experience, and without doubt many patients find themselves in Brown's shoes every day. The ubiquitous nature of this questionable interaction underscores the importance of addressing the issue of informed consent in the context of medical training.

Reconsidering the case

Using the same scenario, let's examine the situation from the perspective of the medical student and patient.

From Smith's perspective, Brown's need for a chest tube represented a golden opportunity for hands-on, supervised training. She was well aware that the interaction benefited her personally in several ways. Not only will her eagerness and skilful performance likely reflect well in her evaluation and make her a more active member of the surgical team, but also the experience she gained will contribute to her own personal goal of becoming a physician who is able to practice medicine safely.

That latter benefit may even help Smith dismiss the uneasiness she experienced when Brown questioned her competence. After all, the knowledge and skill that she had gained, albeit without Brown's explicit consent, will benefit all patients she sees in the future.

And was the patient really exposed to harm? Smith feels confident that the actual risk to the patient did not significantly exceed the risk posed by a resident performing the same procedure. All in all, Smith concludes, performing the chest-tube insertion actually increases the end benefits without causing any increase in potential harm to the patient.

She reasons that, had the resident done the procedure, the patient would have been the sole beneficiary. In this case, while the patient was provided with what Smith perceives to be adequate therapy, there was the added benefit of a contribution to medical education and to other patients who will need competent care in the future. Still, as Smith left Brown's room she wondered if her uncomfortable uneasiness after hearing Brown's question could have been avoided. Should she have told him? Would it have changed anything? She pondered this as she trotted down the hall, trying to catch up to her resident.

The Patient's Perspective

From Brown's perspective, the procedure represented a therapeutic option that he should and will accept because it is the appropriate therapy for his medical condition. He was willing to accept the chest tube, as well as the discomfort it entailed, because a competent medical team he trusted had led him to believe it was the proper course to pursue. As he lay in his hospital bed, slightly short of breath, he tried to reason away his anxiety, tried to remember if anyone he knew has had a chest tube inserted. Is this a risky procedure?

His thoughts were interrupted when the resident and a young woman in a short white coat entered the room. They greeted him politely and introduced themselves. He recognized the resident, but who was this physician-in-training? She was not wearing a name tag. She's probably taking a refresher course in surgery. Or maybe she is simply another resident? Perhaps a student?

As Brown pondered these questions, the resident explained that Smith would participate in the chest-tube insertion. Why not? She must know what she is doing, and Brown has never had any reason to question the trust he bestowed upon his caretakers.

But as the resident and the other doctor begin the procedure, Brown cannot help but notice that Smith's face is turning red with concentration as she prepares, with a trembling hand, the syringe containing the local anesthetic. Has this person ever done this before? She certainly seems nervous, even more nervous than he is, if that's possible. The resident tries to reassure him, but Brown is apprehensive. He's not sure if he wants to continue with this.

It angers him that he did not ask more questions before the procedure started. Exactly who is this physician-in-training? For the first time in his hospital visit, Brown feels betrayed.

Fortunately, the procedure is completed in less time than he expected, and he hardly felt a thing. It wasn't so bad after all. Now he feels foolish now about his anger and apprehensiveness. Still, he could not shake the memory of the fear that squeezed his stomach, or forget the moment when he began to feel unsafe.

Autonomy and Beneficence

At least 2 ethical principles, autonomy and beneficence, are at stake when medical students become involved in patient care. The chest-tube incident makes it quite clear that Brown's rights to self-determination and adequate medical care were not respected.

In order to satisfy the principle of autonomy, patients must be provided with enough information and time to make an informed decision about their care. Sufficient information includes not only relevant details about a procedure but also details about the status and experience of the person performing it. The term physician-in-training does not provide a clear description of competence. Even the term medical student may need to be clarified for some patients.

Moreover, once patients have reached a decision, they must also be allowed to express their wishes, without being coerced, about which therapeutic option they prefer or consent to, and the caretaker must respect that decision.

The “blanket clauses” that patients are asked to sign when they enter a teaching hospital, which state that the patient accepts that part of the care will be provided by people designated by the staff physician, do not replace informed consent.^{1,6} Patients do not waive their right to choose when they enter a teaching institution. In Brown’s case, he should have been allowed to select between letting the resident or the clearly identified medical student execute the procedure, knowing that she would be adequately supervised and that he would be contributing to medical education.

The bottom line? It is the patient’s prerogative, not the physician’s, to decide what is going to be done to his or her body. Clearly, Brown was not given a chance to exercise this right.

For the medical student, informed consent may be perceived as a threat to adequate training because refusals by patients may reduce significantly the number of learning opportunities. At best this is a legitimate but unfounded worry. Even though Article 11 of the Quebec Civil Code indicates that respect for autonomy takes precedence over the provision of “hands-on” training for students, it should not necessarily interfere with the training. Many patients, if they share a trusting relationship with their physician and are given enough reassurance that adequate supervision will be provided, will allow a student to participate in their care.

Moreover, the act of obtaining informed consent could itself be seen as a learning opportunity, not a barrier to medical education, because it implies a high level of communication skills. Surely, these interactive skills are vitally important in the training of ethically concerned, humane professionals.

In order to satisfy the principle of beneficence, caregivers must not cause any avoidable harm to patients in the course of providing them with adequate therapy.

The Case of Mr. Brown

In Brown’s case, it may be reasonable to assume that the risk of harm was not greatly increased because a student performed the procedure. The resident had known her for 2 weeks and was likely justified in deciding that she was ready to attempt a chest-tube insertion, which he would supervise closely.

However, even though the procedure was completed without complications, Brown’s treatment was indeed compromised. When he was deliberately, albeit not forcibly, denied the chance to exercise his free and informed will concerning who was going to insert the chest tube, the therapeutic alliance Brown had come to rely upon had been jeopardized: his trust was shaken, he felt unsafe and some psychologic harm was done that could have been avoided had Brown’s right to informed consent been respected.

It is tempting to minimize the impact of Brown’s temporary insecurity by weighing it against the resulting benefits to the common good. However, the same precarious reasoning could be applied to research that involves test subjects in trials that could be harmful but ultimately may benefit the majority. Informed consent is paramount in such trials.

Similarly, patients should be informed and allowed to choose whether a student participates in their care. The potential impact on medical training does not outweigh the moral, ethical and legal necessity of telling a patient the truth.

The Search for Solutions

Dishonesty can undermine trust within the doctor–patient relationship. It affects patients not only during the medical act but also in the future because it will colour interactions between patients and their caregivers. What is medicine without the trust inherent within it? We must consider ways to promote honesty within medical training.

Perhaps we place too much emphasis on learning how to perform procedures and not enough on learning how to interact with patients. If Brown’s need for a chest tube had been perceived by Smith as a great opportunity not only to learn a procedure but also to sharpen her communication skills, the goals of learning would have been met, at least partially, whether or not Brown had allowed Smith to participate in his care. The value of this experience would extend not only to future patients needing a chest tube but also to any patient requesting information about a procedure or therapy.

We may assume too quickly that most patients, if given the choice, will refuse to let students participate in their care. I could not find a study documenting what proportion of patients refuse to take part in medical education if given the choice, but personal experience suggests that our concerns are exaggerated.

To reconcile the need to provide both adequate training and informed consent, we should think of ways to convince patients that involving students in their care is to their advantage. Siegel makes several valid arguments justifying residents’ participation in surgical procedures.⁷ He cites the need to explain the inherent safety of trainee participation by emphasizing the close supervision it entails, and establishes that teaching hospitals with strong training programs have better morbidity and mortality records than other institutions.

This is logical, because an environment in which staff physicians are constantly challenged by the curious minds of students and residents means the quality of medical care will be maintained at a high level. Finally, several heads are often better than one. In teaching institutions, patients benefit not only from the attention of a staff physician but also have the undivided attention of a brigade of trainees eager to listen to their stories.

Conclusion

The involvement of students in patient care may seem like fertile ground for a disturbing conflict of interest, but a closer look at the issue reveals that patients and medical students are, in fact, “natural allies” who need one another.⁸ Although patients may not fully realize it, medical students are often their most fervent advocates, messengers and listeners. Being at the low end of the responsibility hill, students often have more time to spare, and perhaps more patience.

We have everything to gain from building on the honest base of informed consent within the context of medical training. The argument that education may be jeopardized has no firm foundation in fact. When we avoid disclosing the relevant truth to a concerned patient, we enter a vicious circle that reinforces our prejudices and makes us underestimate people’s incredible willingness to contribute.

We are so concerned that patients will refuse to contribute to medical training we end up making our fears a reality, and we undermine the very trust that gives patients the incentive to accept student involvement in their care.

References

1. Annas, GJ. The care of private patients in teaching hospitals: legal implications. *Bull N Y Acad Med* 1980; 56:403-11.
2. Cohen DL, McCullough LB, Kessel RW; Apostolides AY, Alden ER, Heiderich KJ. A national survey concerning the ethical aspects of informed consent and the role of medical students. *J Med Educ* 1988; 63:821-9.
3. Christakis DA, Feudtner C. Ethics in a short white coat: the ethical dilemmas that medical students confront. *Acad Med* 1993; 68:249-54.
4. Keller Holmes M. Ghost surgery. *Bull N Y Acad Med* 1980; 56:412-9.
5. Cohen DL, McCullough LB, Kessel RW, Apostolides AY, Alden ER, Heiderich KJ. Informed consent policies governing medical students' interactions with patients. *J Med Educ* 1987; 62:789-98.
6. Knapp MB. Legal implications of clinical supervision of medical students and residents. *J Med Educ* 1983; 58:293-9.
7. Siegel JH. Surgical training, quality surgical care, and informed consent. *Bull N Y Acad Med* 1980; 56:433-52.
8. Basson MD, Dworkin G, Cassell EJ. The 'student doctor' and a wary patient. *Hastings Cent Rep* 1982; 12(Feb):27-8.

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Useful Links

- Syed Mamun Mahmud, Aasim Ahmad, "Patients as teaching tools: Merely informed or true consent," *Journal of Academic Ethics*, vol. 7, no. 4 (2009): 255-260. doi:10.1007/s10805-010-9099-7.
- Hyam Bashour, Rima Sayed Hassan, A. Koudsi, "Involving patients in medical education: Ethical issues experienced by Syrian patients," *Education for Health*, vol. 25, no. 2 (November 2012): 87-91. http://www.educationforhealth.net/temp/EducHealth25287-1319294_033952.pdf.
- Sara Rizvi Jafree, Rubeena Zakar, Florian Fischer, et al., "Ethical violations in the clinical setting: the hidden curriculum learning experience of Pakistani nurses," *BMC Medical Ethics*, vol.16, no. 1 (2015): 16. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4369076/>.

Organ Transplantation Ethics

5.1: Living organ donation

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Case for Discussion

Twenty two year old Jalal lives in a small village in Punjab and approaches you seeking help as he knows you work in a hospital. He says that he would like to sell his kidney and has heard that this can be arranged, even though it is against the law. He knows others in his village who have sold their kidneys in the past. Jalal and his younger brother work as labourers for a zamindar and are the bread winners for a joint family of 12 people. Jalal is under substantial debt accumulated over the years to the zamindar who is pressurizing him to return the loan. Selling a kidney can enable him to pay off the debt and Jalal tells you that he understands the risks and benefits of selling his. He is healthy and is not afraid of the operation. He is willing to sign any papers that are necessary so that he can sell his organ.

Do you see any ethical issue in Jalal selling his kidney?

What is the position of the Pakistan Transplant Law regarding organ donation and transplantation?

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Farhat Moazam, "Sharia law and organ transplantation: through the lens of Muslim jurists," *Asian Bioethics Review*, vol. 3, no. 4 (2011): 316-332.

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Sharia Law and Organ Transplantation: Through the Lens of Muslim Jurists¹⁴

Farhat Moazam

A common error made by non-Muslim and Muslim analysts alike is to depict Islam as monolithic and static and Sharia Law or fiqh (Muslim jurisprudence) as uniform and frozen in time. The reality is that there is great diversity in the way Muslims live their lives and a plurality of positions Muslim jurists hold on ethical and legal issues. This article begins with a brief overview of the evolution of Sharia Law and the classical *usul al-fiqh* (roots of jurisprudence), and the tradition of *ikhtilaf* (differences, disagreements) that exists within Muslim jurisprudence.² It discusses how the latter is exemplified in juristic positions on organ transplantation and brain death which range from consensus to dissent based on particular interpretation of the Sharia. The second half of the article consists of a "case report" from Pakistan beginning with a brief narrative of events around the passage of the national Transplantation of Organs and Tissues Ordinance, 2007 in order to stem kidney commerce in the country. It describes a petition against it in the Federal Shariat Court (FSC) of Pakistan arguing that specific clauses of the Ordinance were contrary to Sharia, and discusses arguments offered by jurists and lawyers appearing on behalf of the petitioner and the respondents, the role of physicians, and the final FSC judgement dismissing the petition. This case illustrates that religious positions and rulings are not fashioned in a vacuum but shaped by interplay of perceived boundaries of authority within political and legal systems and existing societal norms.

Sharia Law and *Ikhtilaf-al-Fiqh*

One of the factors that has played a crucial role in the development and moulding of Muslim ethical and legal thought is the nature of the early Muslim community, and the particular historical circumstances including the varied geographical, political, and administrative backgrounds within which Islam evolved. Unlike Christianity that remained a religious community for its first three centuries, Islam was a religious-political force from its inception.³ Its rapid spread beyond the Arabian Peninsula and interface with non-Arab cultures and societies, and political schisms within the growing Muslim community itself, resulted in early challenges for Muslims in the realms of the sacred as well as the profane. Efforts in the attempt to protect the early religious ethos and guard against fragmentation of an expanding empire included the development of Sharia Law, or Islamic Law as it is sometimes referred to. Over time, Sharia Law came to be accepted as a guide for not only religious duties and rituals such as prayers and fasting but also interpersonal and worldly dealings, thus subsuming within it the legal and the ethical pertaining to all aspects of Muslim lives (Hodgson 1977). Ethics therefore became an integral part of Sharia Law with scholars of fiqh (jurisprudence), the *fuqaha*, becoming the locus for ethical discourse and what constitutes right and wrong acts. According to Kevin Reinhart and others, "Islamic Law is the central domain of Islamic ethical thought", and is "not merely law but also an ethical and epistemological system" (Reinhart 1983; Hourani 1985; Sachedina 2009). Most Muslims accept that interpreting and ascertaining the "meaning" of Sharia as related to ethics and law is the domain of *fuqaha* (jurists) rather than of theologians and philosophers.

Sharia Law is religious by nature and considered to flow from the guidance found within a divine Sharia. Difficulties arise however in the ambiguous, and sometimes misleading, usage of connected but not identical terms such as Sharia, Sharia Law or Islamic Law, and the discipline of fiqh (from the Arabic word meaning “discernment”). The word Shara’a as it appears in the Qur’an (Sura 45: Ayah 18), and from which the term Sharia is derived, is an overarching concept referring to God’s appointed way for Muslims to follow in life in order to gain salvation in the hereafter; it is a path that is divinely ordained and therefore immutable (Rahman 1979).⁴ But comprehending what God “wants” from humans and fashioning this into moral principles and legal edicts require human reasoning and discernment. Unlike Sharia therefore, Sharia Law is not a human, social construct undertaken by fuqaha (jurists) that is neither divine nor can it be uniform and static through time. Accordingly, whereas Muslims agree that Sharia is divine and immutable, one finds consensus but also diversity in the opinions of fuqaha in its interpretation and translation into law. This occurs even though jurists employ “classical” sources, usul al-fiqh (roots or fundamental principles of fiqh), as their framework for reasoning and subsequent opinions. Problems arise however when the terms (divine) “Sharia” and (manmade) “Sharia Law” derived through fiqh are used interchangeably, giving a sense of divinity and immutability to the latter (Kamali 2008; Masud 1995).

Sharia Law as it is known today did not exist during the lifetime of the Prophet and the first four Caliphs, but evolved gradually over the subsequent three centuries of the Muslim Empire as it expanded from the Arabian Peninsula to Asia, Africa, and parts of Europe. In the early years, the Qur’an and the Sunna (normative practices, customs) of the Prophet Mohammed and his companions sufficed as the sources from which Muslims drew guidance in both religious and temporal matters (Rahman 1965; Hourani 1985).⁵ In subsequent years, however, Sharia Law came to rest on four foundational principles called usul al-fiqh. The Qur’an and the Sunna (concretised in the form of written reports — Hadith) were accepted as the primary Scriptural sources, but to these were added ijma’ (consensus of jurists) and qiyas (analogical reasoning). The first systematic structure of Sharia Law in this form is traced to Imam Shafi (767–820 C.E.) and his influential *Al-Risala fi Usul al-Fiqh* is considered by many to be the first comprehensive text on Muslim jurisprudence (al-Shafi1987). Influenced by Greek philosophy, the dominant methodology in applying the usul to arrive at opinions became Aristotelian deductive logic moving from the “explicitly known to the explicitly unknown” (Hodgson 1983).

Historical debates regarding the relative role of revealed texts versus human reason in Sharia Law are beyond the scope of this article, but in addition to the four roots, jurists employ secondary principles albeit differences of opinion exist regarding their usage between the madhhab (schools of jurisprudence). Juristic principles, including ijihad (independent legal reasoning), istihsan (preferential reasoning of jurists), ‘urf (local customs), and maslaha (general public welfare) among others, have allowed a degree of flexibility and accommodated a diversity of pragmatic legal rulings based on social context. Disagreements (ikhtilaf) among jurists are seen in a positive light; legal texts record different juristic opinions on the same issue with a specific line of literature devoted to ikhtilaf al-fuqaha.

Many instances are on record of resistance by early jurists against State efforts to establish uniform codes of law binding on all Muslim territories. The most well known of these is the refusal by Imam Malik (715–795 C.E.) to comply with the Abbasid Caliph’s request that the former’s book *al-Muwatta*, a collection of Hadith and commentaries based on practices in Medina, be made determinative for Muslims everywhere. Imam Malik is reported to have said to the Caliph that “the disagreement of the ulema is a mercy from Allah”, and that “each peoples take what was handed over to them, and they yield to Allah with it” (Winkel 2000). Khalid Masud believes that this tradition of juristicikhtilaf is key to understanding the development of the Islamic legal tradition, and can provide “an important juristic tool to reinterpret Muslim family laws” for current times (Masud 2009).

Despite historical and current evidence to the contrary, there is an assumption among some Western writers and Muslim thinkers including jurists, that Sharia Law is immutable and frozen in time, and its application temporally and spatially uniform. The reality is that whereas Muslims agree on matters of 'ibadaat or duties owed to God, when it comes to mu'amalat, matters connected to the temporal world, one finds consensus but also notable differences in the interpretation of Sharia.⁶ The plurality of opinions between, and within, Muslim schools of jurisprudence in ascertaining the legal and the ethical is influenced by geographical and historical differences, cultural and societal diversity, prevailing customs, and the variety of political and administrative systems within which Muslims existed in the past and live their lives today (Rahman 1965; Schacht 1998; Masud 2002; Eickelman 2002).

Muslim Jurists, Organ Transplantation and Brain Death

A recent challenge for Muslim jurists has been to address moral issues that surface with the advances in biomedical science and technology. Accepted as the locus for moral guidance by many lay and professional Muslims alike, jurists are being questioned about the "permissibility", or not, in Sharia of clinical practices including donation and transplantation of human organs and brain death criteria to establish death. To arrive at opinions on medical and scientific issues too, Muslim jurists employ derivative reasoning from the classical roots of fiqh and utilise secondary juristic principles and maxims such as "necessity makes lawful that which is prohibited", and "where it is inevitable the lesser of two harms should be chosen" (Haleem 1993; Kamali 2008: 144–5). An important point to note, however, is that in the absence of a central doctrinal authority like a Church in Islam and the presence of the ikhtilaf tradition, rulings and fatawa (religious opinions) on any matter delivered by jurists from one part of the world or a particular madhhab, while carrying authority, are not considered binding on those who dissent (Kozlowski 1996).

This section provides a brief summary of existing juristic opinions on these two issues and highlights areas of consensus and disagreements.

Solid Organ Donation and Transplantation: The moral and legal dimensions of organ donation and transplantation have been a subject of debate among Muslim jurists and scholars for a number of years, a fact little known to the international bioethics community. One reason for this may be because Arabic remains the dominant language for such discussions and related publications, a language in which few are conversant, including Muslims of whom a majority are not citizens of Middle Eastern countries. What, however, should also not be discounted is that the dominant model of contemporary bio-medical ethics which has gained international currency is of a "resolutely secular orientation" utilising Anglo-American analytic philosophical traditions and focuses on a search for universals in which religion plays no part (Fox and Swazey 2008; Jafarey and Moazam 2010).

Juristic debates on this issue began in the 1980s, and due to the unfamiliarity of most jurists with the complexity of the science involved, Muslim physicians played a key role as "experts" through direct participation in discussions and by providing written submissions. In 1982, following a meeting in Jeddah, the Saudi Grand Ulema sanctioned (a "majority" not unanimous ruling) both living and deceased organ donation. This was followed by a similar ruling by the Academy of Islamic Jurisprudence in its 8th session in their meeting in 1985, by the Conference of Islamic Jurists held in Amman, Jordan in 1986, and subsequently by other jurists in Kuwait and Egypt. Conditions for permissibility of transplantation included voluntary consent of the donor and a medical opinion that no other measure was available to save the patient's life. In 1988, the 4th International Conference of Islamic Jurists held in Jeddah endorsed all previous fatawa about the permissibility of organ donation and transplantation, prohibited organ trading and trafficking as counter to the spirit of Sharia, and emphasised altruistic donation (Albar 1995; Yaseen 1995).

Arguments in support of organ donation and transplantation employed traditional deductive logic beginning from the *usul al-fiqh*, and emphasised the juristic principle of *maslaha* (public welfare) particularly in allowing deceased donation. The sanctity of human life, the priority of saving it when science provides the means to do so, and the duty of believers to come to one another's help were given precedence over other concerns, and supported through analogies with verses of the Qur'an (5:32, 5:2) and Hadith of Prophet Mohammad (Sermons 1400 AH; al-Bukhari n.d.). One fatwa from the Dar al-Ifta' in Riyadh, Saudi Arabia in fact categorised organ donation by Muslims as *fard kifayah* (collective obligation) (Ebrahim 2001).

In contrast to the opinions of jurists from the Middle East, some of their counterparts from South Asia, using the same sources and methodology of argumentation, arrive at different conclusions especially in the case of deceased organ donation. Among these is Mufti Mohammad Shafi, an influential Pakistani jurist (d. 1976) and author of widely read texts (in Urdu) with his opinions covering a wide range of topics ranging from spiritual obligations and religious rituals to blood transfusions, family planning, organ transplantation, modalities of travel, use of modern machines, and banking systems (Shafi n.d., Lahore). Mufti Shafi also summarises his views on organ donation specific to kidneys in a booklet in which he writes that procuring a human organ, from the living or the deceased, for transplantation into another is not permissible in Sharia (Shafi n.d., Karachi).

The arguments he offers in support include the body is not "owned" by humans but is an *amanat* (trust) given by God and so cannot be disposed of as wished; mutilation of a dead body is strictly prohibited based on the Prophet's Hadith that breaking the bone of a dead man is similar to doing so in a living person; a concern that human organ transplantation will inevitably lead to commerce and buying and selling of organs which is contrary to the dignity God has bestowed on humans. Some other *fuqaha* of the Asian sub-continent also hold negative opinions about deceased donation in particular arguing that humans cannot write a *wasiyyah* (will) about use of their bodies following death as the body is not "owned" by them (Rehmani n.d.; Ebrahim2001: 63–4).

The practical implications of these religious opinions regarding organ transplantation, especially in attempts to develop deceased donor programs, are obvious. These rulings are far better known to the *molvis* (men leading communal prayers in mosques), influential opinion makers with access to the masses, as compared to a relatively insular Muslim medical community which is more familiar with and quote opinions of jurists from the Middle East supporting living and deceased organ donation as permissible in Sharia.

Brain Death Criteria: Juridical discussions on brain death criteria also reveal support from the majority but with some dissenting voices. According to Mohammed Ali Albar, a physician in Saudi Arabia, brain death was discussed for the first time in 1985 (some years after the transplantation debates) at the Second International Conference of Muslim Jurists held in Jeddah which ended with the decision that no opinion could be given without further consultations (Albar 1995). However, in their 1986 meeting in Amman, Jordan, a "historic resolution" was issued by "majority vote" accepting brain death as criteria for death in addition to cessation of cardio-respiratory functions. The influence of Muslim physicians in this meeting was again critical. Nevertheless, in the Islamic League Conference of Jurists in Mecca in 1987, jurists refused to "recognize brain death as death" while approving previous *fatawa* allowing organ transplantation. According to Albar, "this decree received little publicity in the media" and provided "no further hindrance" to acceptance of brain death.

A review of the proceedings of the 1986 Amman conference, in which brain death criteria were declared permissible by majority vote, also reveals dissenting voices, a comprehensive analysis of which is offered by Ebrahim Moosa (Moosa 1999). Discussions revolved around the relationship of the soul and the body and indications in the Qur'an and the Sunna that death occurs when the *ruh* (soul) leaves the body. Jurists

in favour of brain death criteria argued that, as the Scriptures did not specify how to pinpoint this moment, it is the responsibility of the “specialists” (physicians) to establish this through use of *ijtihad* (independent reasoning).

On the other hand, jurists opposing brain death tended to use the “literal meaning of the verses of the Qur’an or inferences drawn from it” and rationalised that there was no justification to emphasise one organ (the brain) as the locus for the soul rather than another such as the heart. Moreover, Islamic Law requires that death be ascertained with *yaqin* (certainty) and not through *zann* (legal probability), and death cannot be said to have occurred with *yaqin* “if the body is still pulsating [with a beating heart]”. Concerns were also expressed that the primary objective of brain death was to obtain organs for transplantation, and a day may come when an unconscious or insane person would be included in the category of the dead for this purpose. It is of historical interest that these concerns echo those expressed by Christian theologian Paul Ramsey and philosopher Hans Jonas in the 1970s (Moazam 2006). Jonas in particular worried that “we do not know the exact borderline between life and death”, and that legitimising brain death would “open the road” to a rush for harvesting organs (Jonas 1970).

Kidney Transplantation in Pakistan: A Case Study

This section moves from theoretical debates among Muslim muftis and jurists to jurist arguments in an actual case filed in the Federal Shariat Court of Pakistan challenging clauses of the organ transplantation Ordinance as being contrary to Sharia. It begins with a brief account of events leading up to the promulgation of the “Transplantation of Organs and Tissues Ordinance, 2007” in Pakistan which criminalised all commercial transactions related to human organs, and the subsequent petition filed in the Pakistan Federal Shariat Court (FSC) challenging certain clauses of the Ordinance as being “repugnant to the injunctions of Islam.” An analysis of different arguments offered by Muslim jurists appearing for the petitioner and the respondents will be presented as will salient features from the FSC ruling in which the petition was dismissed.

Organs and Tissue Transplantation Ordinance 2007, Pakistan

Systematic transplantation of kidneys in Pakistan began in the 1980s in the absence of any national and institutional oversight and regulatory bodies. Similar to other developing countries, as the country did not have deceased organ donor program, all transplants were undertaken with kidneys obtained from living donors (Groth 2003). The early pattern of family members donating kidneys for kin was gradually replaced by one in which the major source became impoverished individuals willing to sell a kidney. This shift was driven by private sector physicians and hospitals in the major cities of Punjab increasingly willing to offer transplants to affluent citizens from other countries with kidneys bought from poor, often debt-ridden villagers. By the end of the 20th century, Pakistan had achieved notoriety as a “kidney bazaar” with a handful of physicians and private hospitals running a lucrative business of kidney tourism worth millions of dollars.

At the turn of this century, the Sindh Institute of Urology and Transplantation (SIUT), the busiest public transplant centre in the country, renewed its longstanding struggle for a national law to curb kidney commerce. As reports of exploitation of kidney vendors by hospitals began to rise, the campaign against such practices was taken up by the press and the media, other health-care professionals and associations, and representatives of civil society.⁷ The faculty of the recently inaugurated Center of Biomedical Ethics and Culture in SIUT contributed through publication of ethnographic studies on the repercussions on Pakistani vendors and their families (Moazam, Zaman, and Jafarey 2009), and by submitting letters and articles to the local press for public awareness.⁸ Publications about medical and economic ill effects on kidney vendors, and collaboration with international organisations including the WHO, also served to advance this cause (Naqvi, Ali, and Mazhar 2007). The push for a national law against kidney trade and tourism was met with active opposition from a handful of influential, politically well connected physicians and hospital owners known to be at the forefront of these practices.

In 2006, the Chief Justice of the Supreme Court of Pakistan took suo moto notice of the kidney trade adding to the pressure on the government to act, and in September 2007, the “Transplantation of Organs and Tissues Ordinance, 2007” was finally promulgated through Presidential decree by Parvez Musharraf (Syed 2007). The Ordinance prohibited unrelated living organ donation (exceptional cases are permitted following review by an Evaluation Committee), and criminalised transplantation of organs from Pakistanis into foreigners with stiff fines and imprisonment for those, including physicians, convicted of these offences. It recommended the setting up of a national registry and an oversight body (HOTA — Human Organ Transplantation Authority) and initiation of deceased donor programmes in Pakistan. (The Ordinance was ratified as law unanimously, by both the Pakistan National Assembly and the Senate in 2010.)⁹

Several attempts were made by the organ trade lobby to amend the Ordinance and relax restrictions against non-related donors and payments to those providing kidneys.¹⁰ One of the most significant challenges to it occurred on 26 January 2008 through a petition filed in the Federal Shariat Court of Pakistan claiming that specific clauses of the Ordinance were contrary to the Sharia and therefore should be removed.

Federal Shariat Court (FSC) of Pakistan

Article 203-D of the Constitution of the Islamic Republic of Pakistan stipulates that all laws in the country must conform to “the injunctions of Islam as laid down by the Holy Qur’an and Sunna” (www.pakistani.org/Pakistan/constitution). The FSC of Pakistan was established in 1980 under Chapter 3A of the Constitution by a Presidential Order of General Zia ul Haq, and given the authority “to examine and decide the question whether or not any law or provision of law is repugnant to the injunctions of Islam,” and refer those it considered to be against the Sharia to the Parliament for amendment. The FSC bench consists of eight judges, appointed by the President for three years, drawn from serving or retired judges of the Supreme Court or the High Courts, and of whom three must be well versed in Islamic Law.

Any Pakistani citizen can appeal to the FSC for review of any law of the land (www.federalshariatcourt.gov.pk). The list of cases filed in the FSC reveals range of government laws and ordinances which Pakistani citizens have perceived and contested as being “repugnant to the injunctions of Islam.” Petitions have been filed against Land Reform Regulation Acts, Pakistan Penal Codes dealing with murder and capital punishment, disputes with the government over land and property ownership, banking and interest laws, clauses in Pakistan Family Laws pertaining to guardianship of women for marriage and divorce, among others.

Nevertheless, the establishment of the FSC by a military dictator, the nature and sphere of its function, and many of its rulings, especially those related to the position and roles of Muslim women, have continued to remain a source of major controversies in the country.¹¹ Established to “Islamise” the legal system in Pakistan, one of the earliest actions by FSC was to endorse the “Hudood Ordinances” which Zia ul Haq had decreed in 1979. The clauses in these Ordinances pertaining to punishments for rape, fornication, and adultery have led to severe repercussions for Pakistani women (Moazam 2004). Many believe that the constitution of such a court with total presidential control over appointments and tenure of its judges runs the risk of its functioning as a political tool.

The Chief Justice of the FSC at the time of the challenge to the Ordinance (Shariat Petition No. 1/1 of 2008) was a past Judge of the Sindh High Court and ex-member of the Council of Islamic Ideology of Pakistan (<http://www.cii.gov.pk/>). The Court held seven hearings related to the petition in Karachi and Lahore, all open to the general public, before giving its final judgement in April 2009 dismissing the petition. I attended the proceedings held in Karachi which took place in the cavernous room of a British-era court building in the heart of the city. The room was packed with a mix of people members of the general public, lawyers attired in traditional black jackets and pants, healthcare professionals some in

white coats, and Muslim muftis and jurists in robes and headgears specific to their madhhab with prayer beads in hand. The atmosphere was surprisingly informal despite judges in traditional black robes seated on an elevated dais facing the room. During the hearing, in addition to designated lawyers and jurists appearing for the petitioner and the respondents, others in the room were free to walk up to a microphone facing the judges and make a point. At times, a crowd would gather around the micro-phone while the judges tried to listen patiently to each individual. Languages used were a mixture of Urdu and English with a smattering of Arabic when quoting from the Qur'an and Hadith.

Petitioner and Responders

The petitioner on record was a transplant surgeon and owner of a private hospital in Rawalpindi who was listed as President of the Society of Transplant and Surgeons of Pakistan.¹² The respondents named included the Ministry of Law, Justice and Human Rights, and the Ministry of Health of the Government of Pakistan. Muslim jurists belonging to different religious seminaries in Sindh and Punjab were invited as individual “experts” by both legal teams to appear in person or submit written opinions. The FSC judges, noting the “importance of the subject matter”, had also felt it “necessary to hear Muslim scholars, ulema, juris consults, leading advocates, professors of medicine and eminent surgeons, etc., with request to submit their views orally or in writing.”¹³

Both parties began with the position that living and deceased organ donations are permissible in Sharia, and focused on sections of the Ordinance related specifically to living kidney donors. The petition challenged as “repugnant to Islam” Section 3 and its sub-clauses that restrict living organ donations to blood relatives and spouses of patients; Section 7 that prohibits donation of organs by Pakistanis to citizens of other countries; and Section 11 and its sub-clauses that criminalise all forms of organ commerce and payment to donors, and lay out punishments (fines and imprisonment) for those, including physicians and hospitals, involved in such practices.

Supporting and Opposing Arguments

The following is a summary of arguments made by jurists and lawyers, both frequently quoting the same Qur'anic verses and Sunna, in support of and against the petition to the FSC. For the sake of clarity, the arguments have been organised under sections that were challenged and, where indicated, relevant statements from the final FSC judgement are also included. The FSC proceedings offer an interesting mix of the religious and the secular, of texts (Scriptures) and contexts (local realities).

Section 3 and Sub-Clauses

Those supporting the petition argued that Section 3A restricting kidney donation to only close blood relatives and spouses is repugnant in light of the teachings of the Qur'an and Sunna and should be removed. Human life is considered sacred in Islam and a primary objective of Sharia is to safeguard it. It is therefore the duty of Muslims to save a life when they can and this cannot be limited to a blood relative. The importance of this can be judged by the verse of the Qur'an (5:32) which states that saving one life is akin to saving all of mankind. The Qur'an also declares that all believers are brothers (49:10), that believing men and women are friends to each other (9:71) and so must help one another in what is good and pious (5:2).

A jurist from an Ahle-Hadith seminary in Lahore stated that according to the Prophet's Sunna, “Muslims are like a single soul and have been enjoined to cooperate with each other.” Therefore, it is incumbent on Muslims to help all Muslims when possible and not merely those who are kin. In his statement to the court, the lawyer for the petitioner quoted a WHO report that “at least 200,000 people are on waiting list for kidneys.” Abiding by Section 3, he argued, would therefore mean that, in cases of unwilling or non-matching donors among close relatives, “thousands of kidney patients suffering from renal failure will die off each year,” and this was contrary to Sharia's message that human life be protected.

Those appearing for the respondents also quoted verse 5:32 but chose a nuanced interpretation arguing that the message about the importance of saving human life is of a “general nature,” and “cannot be read in isolation but in conjunction with other verses.” Moreover, the human body and organs are not “owned” by humans but given in trust to them from God, and therefore humans cannot do as they wish with their bodies. God has defined limits for the use of the body and this includes safeguarding it from harm. This has been confirmed through ijma’ (consensus) of previous Muslim scholars who deem it impermissible to risk one life to save another. The respondents’ lawyer emphasized medical data revealing health and socioeconomic harms to unrelated kidney donors as compared to the sense of well-being reported by those who had donated to relatives.

The Administrator of HOTA (also a physician) clarified in his statement that in cases of non-availability of related donors, Section 3(B) allowed donation by a “non close blood relation” following approval by an Evaluation Committee. It was pointed out that in the absence of transplantation, patients with end-stage kidney failure can survive on dialysis for many years. (In their final judgement, the FSC judges, taking note that patients can survive on dialysis, chastised the government for not providing adequate dialysis and transplantation services for its citizens.)

Section 7

Supporters of the petition opposed the prohibition of transplanting foreigners with kidneys obtained from Pakistani citizens on the grounds that this was against Islam’s “standards of humanity.” All humans are equal creatures of God and the Qur’anic verse (5:32) in utilising the word al-nass (humanity, mankind), clearly points to the life of all humans and not just that of Muslims. The Prophet’s last sermon in Medina was quoted in which he is reported to have said that “an Arab has no superiority over a non-Arab nor a non-Arab has superiority over an Arab except in the matter of piety.” The lawyer for the petitioner further argued that Section 7 was also an example of “the worst kind of discrimination” in light of the UN Charter of Human Rights.

Respondents, on the other hand, focused on a different set of clauses in the Charter of Medina, those which emphasise the duty to protect citizens of a city from harm in the hands of outsiders. In their final judgement, the judges too alluded to the Charter and included quotations from it such as, “Believers are protectors of one another to the exclusion of other people,” and “No neighborly protection shall be granted to the Quraysh [persecutors of Muslims] nor to those who help them”. In the judges’ view, as the objective of the Ordinance was to protect Pakistan’s “poverty stricken people” from “rich foreigners who find Pakistan a safe haven for kidney trade,” Section 7 was in conformity with the objectives of Sharia. The FSC ruling also added that the “Constitution of Pakistan under Chapter I of Part II provides fundamental rights to its citizens which may not necessarily be extended to foreigners.”

Section 11 and Sub-Clauses

The petitioner objected to the prohibition of payment to kidney donors arguing that monetary compensation for human organs is permissible in Sharia. A jurist reported that in the opinion of muftis belonging to the Jama’ Darul Uloom seminary, “it is permissible to save the life of any individual and to receive donation, gift or prize money in lieu of a kidney.” (He did not differentiate between the three and was not asked to do so.) A Muslim scholar belonging to Fiqh Jafaria (the Shi’i madhhab) was quoted by a jurist as having permitted monetary compensation for human organs used for transplantation.

To support payment for human organs, jurists drew analogies from juristic rulings of the 9th–10th centuries related to the buying and selling of slaves. Muslim scholars from the more recent past, including Mufti Shafi of Pakistan, who have ruled that payment for human breast milk and blood is permissible in Sharia were quoted, and arguments offered that this was analogous to paying money to acquire human organs. (Mufti Shafi’s opinion that living and deceased human organ donations are impermissible in Sharia was not mentioned.) Finally, some argued that as human life is sacred and must be preserved at all costs,

jurists have ruled that in order to do so, even otherwise impermissible actions, such as eating the flesh of swine, become permissible in Sharia.

Those opposing the petition gave a range of arguments to rebut that this clause was contrary to Sharia — according to Sharia, humans are not “owners” of their bodies, God is, and it is forbidden to sell something you do not own; selling a part of the body converts it into commodity and violates the Qur’an’s emphasis on the dignity bestowed by God on all humans; human milk and blood are replenished by the body and so are not analogous to human organs such as kidneys; the juristic maxim that “necessity knows no law” cannot be used to support acts that transgress boundaries set by God such as man’s relationship to his body which is one as a trustee and not owner.

The lawyer for the respondents also emphasised the *ijma’* of Muslim jurists that buying and selling of human organs is impermissible in Sharia, quoting as examples rulings by the Islamic Jurisprudence Fiqh Academy, Islamic Fiqh Council, the Organization of Islamic Conference, and the Council of Muslim Scholars in Great Britain. He (and some physicians) also presented guidelines and declarations by international professional organisations such as WHO and the Middle East Society of Organ Transplantation (MESOT) that strongly oppose any form of commercial transactions for human organs.

The Verdict

On 20 April 2009, the judges of FSC dismissed the petition in a unanimous ruling and also recorded an additional argument in which they applied another religious idiom to a contemporary situation. They noted that the worldwide treaties of modern times did not exist during the lifetime of the Prophet but the Qur’an and the Sunna emphasise “the great sanctity and importance” of treaties. It is therefore the duty of Muslims to adhere to the terms of covenants and promises they make (Rosen 2000).¹⁴ Pakistan is a signatory to the WHO, and the World Health Assembly in 2004 had clearly advised member States “to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs.” Therefore, as an Islamic Republic, Pakistan was morally bound to honour this agreement.

In August of the same year, the petitioner appealed to the FSC, requesting review of the verdict, but the appeal was dismissed. In November 2009, he filed a petition against the verdict of the FSC in the Supreme Court of Pakistan but withdrew it in August 2010 prior to a hearing.

Discussion

The proceedings of the FSC provide a glimpse into how Muslim jurists (and judges) attempt to apply Sharia Law in an actual society as compared to theoretical debates and opinions that emerge from their counterparts in Islamic academic conferences. Arguments constructed by supporters and opposers of the petition highlight the paradox inherent in the nature of Sharia Law as it has evolved over the years. On the one hand, Sharia Law has a capacity for a degree of flexibility due to the historical tradition of juristic *ikhtilaf* (differences, dissent) and employment of secondary, context-based judicial principles such as *maslaha* (public benefit). This can allow a dynamic process, making possible pragmatic rulings to effectively address issues faced by contemporary Muslims. On the other hand, Sharia Law is also home to rigid Scriptural literalism and a belief that it is possible by employing deductive logic to extract from “words” (the essence of which is often ethical rather than legal) positive laws that can address every situation, even in a world that is vastly different, and far more complicated, than the one in which Sharia Law evolved (Rahman 1998).¹⁵

These two faces of Sharia Law are discernible in the arguments offered by the protagonists in the FSC case. To establish legitimacy, jurists, and equally the lawyers, referred to one or more of the roots of *fiqh* — the Qur’an, the Sunna of the Prophet, previous *ijma’* (agreement) of jurists, or *qiyas* (analogy). Those appearing on behalf of the petition generally began with literal words from the Qur’an or Hadith and then attempted by feats of analogy to find a “technical fit” within these for the issue being discussed. No extra-

linguistic considerations or contextual features such as existing realities for those who supply kidneys in Pakistan were taken into account. This approach was exemplified by jurists quoting centuries-old rulings connected to the buying and selling of slaves (slavery is illegal in every Muslim country), or the Arab custom of paying wet nurses, as analogies to support monetary payment for human organs. (This is similar to rulings that deceased organ donation is impermissible based on the Prophet's words that breaking a bone in a dead man is as wrong as in the living, while disregarding the fact that he said this to bring to an end the Arab custom of mutilating the bodies of enemies killed in battle.) Such literal, context-free deductions from textual sources are now also being increasingly criticised by contemporary Muslim scholars in Pakistan who argue for a historical and hermeneutic understanding of the Scriptures (Naqvi 2009; Ahmed n.d.).

In contrast, those opposing the petition while also using the Qur'an and Sunna as reference points tended to construct contextual, teleological arguments that emphasised juristic principles such as *maslaha* (public welfare) (Masud 1995; Hallaq 1999).¹⁶ Moreover, unlike the lawyer for the petitioner, the respondents' advocate made a point of highlighting existing social and economic inequalities in Pakistan, and the extreme poverty and large debts among those who sell their kidneys. He utilised data provided by physicians to highlight physical and economic harms to the vendors, and the damage to the country's reputation if it became the hub for kidney tourism again.

However, other factors, besides perhaps the better prepared and more convincing arguments by the respondents' lawyer, also contributed to the trajectory and outcome of this case. The Ordinance was challenged at a time when it had support from civil society as well as the press and the media. It was also known that the Chief Justice of the Supreme Court of Pakistan himself had taken *suo moto* notice of the kidney trade previously helping to increase pressure on the government with the eventual promulgation of the Ordinance. Moreover, three respected medical associations of Pakistan had signed up as parties opposing the petition, and a group of influential SIUT physicians, pioneers of kidney transplantation in Pakistan, remained active and visible in all FSC hearings.¹⁷ In Pakistan, in the eyes of many, the practice of medicine remains a sacred profession with physicians commanding immense respect as God's instruments on earth (Moazam 2000). In addition to this, with a strong Islamic legal tradition of recognising *ahl al-ikhtisas* (the "specialists"), jurists accept the authority of health professionals of repute in all matters pertaining to medical science and practice. Thus, it can be argued that the professional and ethical reputation of physicians appearing against the petition served in significant ways to determine the direction of the FSC discourse and the final decision.

Clearly, the proceedings of the FSC cannot be reduced to a pristine "religious" debate between Muslim jurists and lawyers occurring in a vacuum, nor can the judges' ruling be reduced to theoretical considerations of Scriptural interpretations and methodological approaches to the Sharia. The nature and substance of theological and legal debates have always occurred in the background of struggles for space, authority, and legitimacy between religious traditions and new, emerging political systems and the State. From the 20th century onwards, this has been the case especially in Muslim countries escaping colonial rule where traditional Islamic legal structures exist in tension with Constitutions and elected parliaments, functioning civil and criminal court systems, other spheres of authority, as well as demands of changing societies (Kelsay 2003). In the case of the FSC and the challenge to the transplant Ordinance, it would seem that these factors as much as anything else helped to shape the form and content of the proceedings, calibrate the responses of the judges, and led to the unanimous dismissal of the petition.

Notes

1. Portions of the material in this article were presented at an invited lecture at the Ethical, Legal and Psychosocial Aspects of Organ Transplantation (ELPAT) Conference held in April 2010 in Rotterdam, The Netherlands.
2. This article limits itself to addressing Sharia Law within the Sunni legal tradition and does not discuss its equally rich counterpart in Shi'i thought.
3. Following his migration from Mecca to Medina in 622 C.E., Prophet Mohammed served both in the capacity of religious and spiritual guide as well as statesman and administrator. For elaboration of his dual role, see Rahman (1979: 14–28) and Kelsay (2003: 6–9).
4. Fazlur Rahman differentiates between the concepts of God's divine Shara'a, literally the "path to water," which is the ethical message of the Qur'an, and fiqh which developed later into a juristic science to discern the nature of this path Muslims must follow (Rahman 1979). He also analyses the concretisation of early "living Sunna" (customs and practices) of the Prophet and his companions into Hadith (recorded reports) which assumed a determinative role in Imam Shafi's system of jurisprudence.
5. According to Rahman, in the early years, the Qur'an and the Prophet's Sunna were "creatively elaborated and interpreted" by Muslims to meet new social issues that arose with the spread of Islam, and in Hourani's opinion, these two sources provided early Muslims with a form of "normative religious ethics".
6. Muslims agree on the "five pillars" of Islam which are considered duties owed to God. These are belief in one God and Muhammad as His Prophet, daily prayers, fasting during the month of Ramadan, zakat (mandatory "wealth tax" for Sunnis), and the performance of Hajj if one can afford it.
7. The struggle against kidney tourism and institution of a national law criminalizing such practices were led by the Sindh Institute of Urology and Transplantation (SIUT) in Karachi and its influential director Adibul Hassan Rizvi. For examples of the role played by the press in raising public awareness, see Stop This Heinous Kidney-Selling Racket, Daily Times, 24 May 2007, Pakistan; Ansari, A. (2007) Kidney Donor Has the Worst of Both Worlds, Dawn, 10 July, Pakistan; and PMA [Pakistan Medical Association] Seeks Curbs on Illegal Organ Transplants, Dawn, 11 November 2006, Pakistan.
8. The Center of Biomedical Ethics and Culture (CBEC) in SIUT, inaugurated in 2004, is the only centre in Pakistan dedicated specifically to ethics related education and research relevant to the country (Fox and Swazey 2008: 265–81). Its objectives include raising public awareness about national issues through conferences and articles in the press. On the issue of kidney tourism, see Moazam, F. (2006) Organ(ised) Crime, Dawn, 27 August, Pakistan.
9. The full text is available at www.na.gov.pk/acts/act_2010/transplantation_human_organ_act2010_170310.pdf.
10. Three female parliamentarians submitted a Private Members' Bill in the National Assembly on 26 August 2008 seeking amendments in Ordinance clauses relating to criteria for live donors and impermissibility of monetary payment to donors. This was eventually withdrawn in January 2009 following counter lobbying in which SIUT played a leading role.

11. Controversies around the FSC focus on the circumstances around its establishment (by a military dictator), appointment of judges at the discretion of the President, and the authority to demand removal of any law it deems to be against the Sharia. For many in Pakistan, rulings by the FSC related to personal and family laws have been particularly detrimental to women. It has also been criticised recently by the legal fraternity as an unnecessary parallel judicial system encroaching on the powers of the high courts and the Supreme Court of Pakistan. See FSC Assumes Powers of High Courts and SC, Says Asma, Dawn, 2 January 2011, Karachi. Asma Jahangir is President, Supreme Court Bar Association, Pakistan.
12. The petitioner, a retired army colonel Mukhtar Hamid Shah, is the owner of a private hospital in Rawalpindi commonly known to undertake kidney transplants in foreigners prior to promulgation of the Ordinance. Kidney vendors we interviewed named this hospital among those to which villagers were directed to undergo nephrectomy for sums of money (Moazam, Zaman, and Jafarey 2009). The Society of Transplant and Surgeons, Pakistan, of which Shah is president, has no internet contact or website.
13. Adibul Hassan Rizvi (the then President of the Transplantation Society of Pakistan) and Ali Anwar Naqvi from SIUT, and Farhat Moazam from CBEC were included by FSC as “experts”, and the Human Rights Commission of Pakistan was appointed *amicus curiae*. The Pakistan Association of Urology Surgeons, Transplantation Society of Pakistan, and Pakistan Society of Nephrology requested and were permitted to join as parties in opposition to the petition.
14. Anthropologist Lawrence Rosen has studied Islamic Law and its application in contemporary Moroccan courts over three decades. He argues that the Qur’an and the Prophet’s Sunna place great importance on covenants and contracts as “fundamental relational bonds among reasoning beings” and the maintenance of commitments as “central to moral stature” of humans.
15. Many Muslim scholars argue that the Qur’an is primarily a source of guidance for a just society and not a book of law. Similarly, Rahman believes the message of the Sharia to be ethical and moral in nature and criticizes jurists for being “dusty dry literalists” concentrating on the letter of the law at the cost of the moral essence.
16. Among renowned Sunni Muslim jurists in the past who gave importance to inductive reasoning attentive to existing circumstances and social norms is the 14th century Maliki jurist Shatibi. He is known for using *maslaha* (public welfare) not as a secondary juristic tool but a primary principle together with the classical *usul al-fiqh* to achieve the *maqasid* (goals) of Sharia (Masud 1995: 117–20).
17. SIUT and its faculty and staff generate tremendous respect, and the director Adibul Hassan Rizvi is an iconic figure in Pakistan. The institution undertakes the largest number of transplants with living, related donors, and does so free of all costs to the patient. Rizvi was allowed by the judges to give a presentation (complete with Power Point slides) about kidney transplantation in Pakistan. An ethnographic study of the culture of this institution and its relationship to Pakistani society was published as a book, *Bioethics and Organ Transplantation in a Muslim Society* (Moazam 2006).

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Jamshed Akhtar, "Ethical issues in voluntary kidney donation,"
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Ethical Issues in Voluntary Kidney Donation

Jamshed Akhtar

Abstract

Voluntary organ donation is considered to be a moral act as this may save life of a moribund patient. With advancement in technology both in the field of medicine (pharmacology, anesthesiology and surgery) and nursing care, increasing number of patients with end stage renal disease are surviving with improved quality of life. Though such a change in disease outcome is appreciable but a host of ethical issues have surfaced in relation to voluntary live kidney donation. Many countries have made legislation in addition to awareness creation programs so that menace of unethical practices could be addressed. Recently news has been published in daily Dawn Karachi (June 2, 2009) where a voluntary Pakistani donor has approached the court of law in Lahore with a desire to donate his kidney to a Saudi national. Such cases are rarity in Pakistani courts. This article discusses various ethical values that can be debated while legal issues are left to the court to decide.

Key words: Renal transplantation, Ethical issues, Transplant tourism

Introduction

Various attempts at renal transplantation have been made in the past but the first successful human transplant was made in Boston in 1954. It was performed between identical twin brothers. With improvement in immunosuppression the survival of graft has increased and so is the quality of life of the recipients: Kidney donation. Is preferred form of treatment for end stage renal disease in comparison with repeated sessions of dialysis.¹ While debate is ongoing among religious circles about permissibility of both living and cadaver organ donation, the live organ donation is an established program in Pakistan. The results are at par with advanced countries, with improved survival rates.

Recently an increasing trend of foreigners seeking kidney donors in Pakistan has been reported in national press and electronic media. This has led to formulation of an ordinance where restrictions have been imposed on Pakistani nationals to donate organs to people of other nationalities.² On June 2, 2009 a news was published in daily Dawn Karachi which has raised alarms among civil society.³ This news is basis of this article where ethical issues related to voluntary organ donation shall be debated.

News Story

According to the news a citizen approached Lahore High Court to get the permission to donate his kidney to a Saudi national. The petitioner is a resident of a city in the northern part of Punjab province of Pakistan. The petitioner also claimed that he has a genetic tissue match with Saudi national who according to him is in a need of kidney transplant.

He wants to donate his kidney voluntarily and on humanitarian grounds.³

Debate

The two words used in the news "voluntary" and "humanitarian" are the key points that will be elaborated. Who can take voluntary decision? Only person with a sound mind who could decide for himself, after adequately comprehending the information provided to him in sufficient detail, without undue coercion or inducement can make voluntary decision.⁴ Voluntary nature in this particular case has to be established in the background of criteria provided above. If one passes through this ethical filter then this particular act will be regarded as altruism.

Altruism can be considered as a highly moral act for an unrelated living kidney donation. This altruism can be the result of religious belief in this part of the world where sacrifices for beneficence of others, are considered highly dignified act. By donating one's organ an individual may feel accomplishment of religious duty and this may raise his self esteem.⁵ This act must be autonomous and as pointed out earlier without coercion and inducement. An autonomous decision of an individual is therefore given a respect. As this situation is not observed very frequently and in present case where two I persons of different nationalities living thousands of miles apart had already had tissue match done, raises concerns. To address this issue a person with medical background can be appointed to ascertain donor's understanding of the risks and benefits of organ donation. The elements of coercion and inducements can also be picked up. In this regard a social worker experienced to deal with such cases, should be assigned a task to assess the situation. In addition an opinion from a psychologist would also be of help.

Interesting argument is put forward by some who are of the 'view that organ selling be allowed for commercial purposes. They consider an organ as property of individual thus gives it a commodity status. Commodification and ownership thus are debated in this argument.⁶ But should organ of an individual fall into category of property and thus, commodity. This is not so. Thus selling argument does not have ground. In other argument it was debated that for a society to prohibit something, harm must be proven. Potential or actual harm to kidney donor is well documented. An individual has to undergo anesthesia and surgical procedures with all possible risks. He then has to spend rest of his life in a carefully' planned style so that other kidney is not overburdened. It has also been reported in literature that those individuals who have sold their organs for whatever reason, later developed low self esteem and went into depression. The very act of selling their body parts haunted them like anything. They felt their dignity is lost by committing such an act.⁷

In the recent past two doctors from United States put forward' an argument for a flowing sale of organs _so as to save life of people who could benefit from this act. But it met with great resistance. The reason being probably it will always be poor selling organs for rich people. Thus rich will remain healthy and poor will suffer. This will lead to inequality in terms of health status and kidney bazaar will open up.^{8,9}

The potential of harm to the recipient is also a real threat. A desperate patient in a need of transplantation especially when there is a long waiting list and few grafts available can lead to seeking treatment at places not suitable for such purposes. There are reports where it was shown how recipients were wronged in the name of transplantation and significant harm has been inflicted upon them. There are reports of mortality and transmission of diseases from donor to recipient as procedures were done undercover in resource poor settings. It is thus important that one who seeks donations must be aware of all the potential threats to his health. Thus risks and benefits must be put across to him. In a disease condition especially a chronic one, an individual becomes vulnerable and may not be able to comprehend such potential threats.¹⁰ There is a possibility that the people involved in such businesses may cloud thinking process of such patients by providing them incomplete information.

Distributive justice and equity are other issues that are borne out of this news. The healthcare system must function optimally to provide' treatment in best possible way, across the board. This is a social responsibility of all the governments in the best interest of its people. Some may be able to afford all

possible treatments while others are forced to sell their organs to be able to get basic human needs. There are reports from Pakistan where individuals have sold their kidneys to payoff their debts.¹¹

One of the stake holder in this debate is a transplant physician. He has an obligation to care for his patients. In doing so he must consider beneficence of the recipient but at the same time must not forget nonmaleficence to the potential donor. He has to ensure balance between these two values so that justice should prevail. Poor must not be used as a means to provide good for an affluent person. In fact poor is vulnerable by virtue of his low socioeconomic status which thus can be exploited easily. Here Kantian approach is most suitably applied.¹²

Epilogue Transplant 'tourism' typically refers to the practice of traveling outside the country of residence to obtain organ transplantation.¹³ The World Health Assembly (WHA) issued a resolution in 2004 where it made imperative upon its member states "to take measures to" protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs." This document needed more focused approach though it did point out the direction.¹⁴ In 2008 The Istanbul Declaration was pronounced. It is more comprehensive document that addresses issues related to transplantation of organs in a comprehensive way and provides practical guidelines in dealing with the issues.¹⁵ It is hoped that such an endeavor would go a long way in promoting ethical practices in medical field of organ transplantation.

References

1. Kaufman DB. Renal Transplantation (Medical). Emedicine 2009 available at <http://emedicine.medscape.com/article/429314-overview>.
2. Pakistan, Government. The Transplantation of Human Organs and Tissues Ordinance No. XLIII, 2007.
3. Pakistani kidney 'donor' & Saudi recipient. 2009; June 2 available at <http://www.dawn.com/wps/wcm/connect/dawn~content-library/dawnthe-newspaper/letters-to-the-editor/pakistani-kidney-donor-saudi-recipient-769>.
4. Emanuel EJ, Wendler D, Grady C: What makes clinical research ethical? JAMA 2000, 283:2701-11.
5. Mueller P, Case E, Hook C. Responding to offers of altruistic living unrelated kidney donation by group associations: an ethical analysis Transplantation Reviews 2008; 22(3):200-05.
6. Cline A. Selling Organs for Transplants: Commodification and Ownership of Bodies available from <http://arheism.about.com/od/bioethics/a/sellingorgans.htm>.
7. Moazam F, Zaman RF, Jafary A. Conversations with Kidney Vendors in Pakistan: An Ethnographic Study Hastings Center Report 2009; 39(3):29-44.
8. Should Sale Of Organ Be Legalized? 2006; February 16 available at http://www.medindia.net/news/view_news_main.asp?str=2&x=7893.
9. Rehman F, Grisanti. Pakistan's kidney bazaar. NBC News' 2007; September. available from <http://worldblog.msnbc.msn.com/archive/2007/09/05/345490.aspx>.
10. Gill J, Madhira BR, Gjertson D, Lipshutz G, Cecka IM, Pham PT, Wilkin'son A, Bunnapradist S, Gabriel M. Transplant Tourism in the United States: A Single-Center Experience': Clin JAM . Soc Nephrol 2008; 3: 1820-8.
11. Ilyas M; Alam M, Ahmad H. The Islamic perspective of organ donation in Pakistan. Saudi J Kidney Dis Transpl 2009; 20: I54-6.
12. Denis L. Kant's formula of the end in itself: Some recent debates. Philosophy Compass 2007; 2(2): 244-57. (Abstract)
13. Delmonico FL. The Hazards of Transplant Tourism. Clin JAM Soc Nephrol 2009; 4: 249-SO (Editorial).
14. Human organ and tissue transplantation. World Health Assembly Resolution 2004; 57.18 available at http://www.who.int/gb/ebwha/pdf_files/IWHAS7/AS7_R18-en.pdf
15. Istanbul declaration on Organ Trafficking and Transplant Tourism. 2008; Available at <http://www3.svlis.se/sektioner/tp/fnytt/Declaration%20t%20Istanbul.p>.

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Farhat Moazam, Riffat Moazam Zaman, Aamir M. Jafarey, "Conversations with kidney vendors in Pakistan," *Hastings Center Report*, vol. 39, no. 3 (2009): 29-44.

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Conversations with Kidney Vendors in Pakistan

Farhat Moazam, Riffat Moazam Zaman, Aamir M. Jafarey

In theory, a commercial market for kidneys could increase the scarce supply of transplantable organs and give impoverished people a new way to lift themselves out of poverty. In-depth sociological work on those who opt to sell their kidneys reveals a different set of realities. Around the town of Sarghoda, Pakistan, the negative social and psychological ramifications of selling a kidney affect not only the vendors themselves, but also their families, communities, and even the country as a whole.

Until lions have their own 'story tellers,' tales of a lion hunt will always glorify the hunter. -African Proverb

The growing concern about the shortage of kidneys available for transplantation has led some physicians, economists, and bioethicists to call for monetary inducements and "regulated" organ markets as a way of expanding the number of kidneys obtained from living, unrelated individuals.¹ Proponents of a commercial model for organs formulate their arguments in the language of supply and demand. They believe that "scarcity" of commodities-in this case, kidneys-can be addressed through the use of market forces. In this view, a vendor is an autonomous agent with the freedom to make choices, including the decision to sell a kidney, and depriving impoverished people of the option to sell a kidney makes their bad situation even worse.² In contrast, those opposed to the idea of organ sales believe that such practices lead to exploitation of the most vulnerable people in society for the benefit of the privileged. Concerns are also expressed about the negative repercussions of organ commerce on altruistic donations and integrity of the medical profession, and the weakening of efforts to initiate and sustain deceased donor programs. The potential for increased complications in recipients receiving bought kidneys is another consideration.

These debates are taking place against the backdrop of expanding organ commerce and tourism. Private health care institutions located particularly in Asian countries are advertising "transplant packages" with kidneys bought from the most economically deprived individuals. In a business that runs into millions of U.S. dollars annually, such kidneys are being transplanted not only into nationals but ever more frequently into citizens of affluent countries who travel to the host countries specifically for this purpose.⁴ Despite the increasing awareness of the international organ trade, there is a surprising paucity of original research and scholarly work on this issue. In his presentation in May 2007 at the Second World Health Organization Global Consultation Meeting on Human Transplantation in Geneva, Yosuke Shimazono said he had found only 309 "relevant" documents, of which 243 were media reports, in a review of the previous five years' worth of literature. He emphasized the need for "further medical and social scientific research," without which he thought this "global health issue" could not be addressed effectively.⁵ One of the crucial missing pieces in the literature is in-depth sociological work on the vendors-the men and women who opt to undergo nephrectomy for money- and the on-the-ground realities that frame their decision. Very little is known about the sociological and psychological effects on vendors and on the families and societies they belong to when faced with a situation in which the only way to

address financial difficulties is to sell a kidney. The most outspoken anthropologist to focus on this issue is Nancy Scheper-Hughes, who provides ethnographic accounts of kidney vendors from countries as diverse as South Africa, Israel, Moldova, the Philippines, and Brazil.⁶ A handful of empirical studies from India, Iran, and the Philippines also venture beyond the medical paradigm and quantitative data to explore the psychological repercussions on kidney vendors and their kin.⁷

No studies of this nature have been undertaken in Pakistan, a country that came to be known as one of the largest "kidney bazaars" in the last decade. Almost all publications dealing with organ transplantation focus on medical issues, and especially on the morbidity and survival rates for the recipient and occasionally the donor.⁸ In Pakistan, except for one recent survey of the socioeconomic status of vendors, it is not health care professionals but the local media that have tried to establish direct contact with vendors, often leading to sensational news reports and documentaries.⁹ The only detailed ethnographic study available on kidney transplantation in Pakistan, published in 2006, deals with related, living donors and their families and does not focus on organ trade.¹⁰ The primary objective of our ethnographic study is to broaden what we believe to be a reductive and largely utilitarian international debate on organ commerce and regulated markets that considers the issue as a matter between two individuals—a recipient and a vendor. Such discussions generally highlight the predicament of those patients who wait for years to be transplanted, and often die while waiting. This is understandable, as many supporters of kidney commerce, of one variety or the other, are concerned with the care and welfare of such patients and consider themselves their advocates. In contrast, the would-be providers of these kidneys for transplantation appear as faceless individuals merely exercising their right to sell an organ. Very little is known about the experiential and psychosocial dimensions associated with the decision to sell a kidney or about the possible ramifications of the decision for families, communities, and perhaps even the ethos of the societies in which they reside. Our aim is to turn the light on those who sell kidneys. Our research provides a "thick" description of the lives of kidney vendors and their families in Pakistan, people who stand at the center of organ commerce and yet have remained largely invisible.¹¹ We attempt to open a window into their lives, to capture through their narratives what it "means" to them and their families when circumstances compel them to sell a kidney, and the ways in which this act affects connected existences.

We hope to clothe with flesh and context a global discourse on organ commerce and trade that has mostly employed a narrower, philosophical language revolving around autonomy, choices, rights, and competing interests of abstract individuals.

Kidney Commerce in Pakistan

Systematic kidney transplantation in Pakistan began in the late 1980s in the absence of a national law to regulate it.¹² Initially, because there was no deceased donor program (still the case today), the majority of transplanted kidneys were donated by family members, but by the late 1990s kidneys donated but by the late 1990s kidneys donated by kin had been almost entirely replaced by kidneys bought from unrelated individuals from villages located around major cities. By 2003, most kidney transplants were undertaken in private hospitals in the cities of Punjab. With middlemen working closely with hospitals, economically disadvantaged people from villages became the main source for the approximately two thousand kidneys transplanted annually in Pakistan.¹³ Due to regional geopolitical events, there was a concomitant increase in kidney transplantations undertaken for citizens of countries from the Middle East, Europe, and North America, providing a lucrative business for private hospitals in Punjab.¹⁴

Although occasional cases of kidney selling or "stealing" have been reported in the press from other parts of Pakistan, the systematic practice of "kidney tourism," as it has become known, has remained limited to private hospitals in Punjab.¹⁵ Several reasons may have contributed to this. One has to do with poverty. Punjab is the most densely populated province of Pakistan, and with its rich, fertile agricultural lands has often been called the "breadbasket" of the country. Wealthy zamindars (landowners) own large tracts of

agricultural lands and orchards that are passed from one generation to the next. In this feudal system, large numbers of laborers and workers are needed to tend the lands and take care of cattle. Together with their families, laborers live and work on these lands for wages ranging from Rs. 3,000 to Rs. 4,000 (approximately \$50 to \$60) per month. In addition to meager salaries, the only other benefits provided to laborers include accommodation (often one room) on the lands, a quantity of grain from harvests, a set of clothes, and one pair of shoes.

Workers accumulate debts in the form of loans taken from zamindars, and these loans are impossible to pay back. Even if a portion of the debt is paid off, further loans become necessary for new expenses, including health emergencies, marriages, and deaths. As long as the debt persists, and in spite of the fact that bonded labor is a crime in Pakistan, the worker and his children remain effectively "bonded" to the zamindar and are unable to leave. Punjab also has many brickmaking factories that draw laborers from rural areas of the province; they, too, are provided daily wages insufficient for their needs. Laborers on the farms and kiln workers from factories are among the poorest in Pakistan, and many vendors are drawn from these two communities.

But poverty in Pakistan is not limited to Punjab, so undoubtedly other factors are also at play behind the provinces flourishing kidney trade. Following Karachi (population fifteen million people) in Sindh, Lahore and the "twin cities" of Rawalpindi and Islamabad in Punjab are the next most populated cities in Pakistan. Over the last two decades, there has been a movement in Pakistan to privatize health care, and it has been most pronounced in larger cities with affluent populations. Kidney transplantation, because it is a lucrative service, is of obvious interest to private sector institutions that have resources and trained transplant physicians. Sindh, the other province with an expanding private sector, has not experienced systematic development of organ trade and tourism, however, perhaps because of the influence of the Sindh Institute of Urology and Transplantation, a public sector institution in Karachi that performs large numbers of kidney transplants but accepts only family donors. SIUT draws patients from all over Sindh and to some extent from other provinces of the country.¹⁶

The Study

Selecting and gaining access to subjects. Our selection technique consisted of purposive sampling of kidney vendors considered most likely to provide rich, in-depth information.¹⁷ Subjects were selected from deras (clusters of dwellings) around the town of Sargodha, which is known as a hub for vendors. It was suggested to us that vendors are easily reached through middlemen in the organ trade, but we decided to not take this easy route because of ethical concerns about working with people we saw as part of the organ trade circle. We were uncomfortable about the integrity of the middlemen and uncertain about mechanisms they might employ to convince vendors to meet with us. We also believed that the nature of the information we required would be more reliable if we entered local communities, with the help of their members, and met subjects in their own surroundings rather than having them brought to us. This required locating reliable contacts through phone calls to nongovernmental organizations and acquaintances in and around the area and a visit to Sargodha to meet relevant people.¹⁸

Process and methodology. Our research team consisted of two physicians from SIUT and a clinical psychologist from another university in Karachi, and the research proposal was approved by the Ethics Review Committee of SIUT. The study was carried out during three field visits to the site in 2007, each lasting from four to five days.¹⁹ Our interactions with vendors and families took place within or in the vicinity of their houses or their work sites, and a community member was always present to introduce us. Verbal consents, and all interviews, were undertaken in Urdu or Punjabi (the local dialect) by one of the three primary researchers. To avoid intimidating participants, no tape recorders were used. We believe that for all these reasons, most vendors and their families were relaxed and willing to speak with us frankly and at length. No monetary incentives were offered, but participants were told that we would

check their blood pressure and screen their urine. Anyone judged to need further examination would be provided referral slips for physicians in Sargodha, and treatment and medications would be provided free.

A questionnaire was used to record factual data, and open-ended questions were employed to encourage vendors to talk about the nephrectomy and their perceptions of life since surgery. Attempts were made to record the exact words, terms, and often rich analogies used by the interviewees. The two female researchers in the team met separately with male vendors' wives and female family members. The Self Reporting Questionnaire developed by the World Health Organization was administered by the psychologist to screen for psychiatric problems. A brief test (twenty items) translated in Urdu and consisting of simple yes and no answers, the SRQ has been used and validated in rural and illiterate communities in Pakistan in screening for anxiety and depression. A score of seven to eight or above was selected as significant, as sensitivity and specificity have been found to be above 70 percent at this level.²⁰ Blood pressure readings were obtained with a manual sphygmomanometer, and a "dip stick" urine examination was used to test for the presence of sugar, protein, bilirubin, and blood.

Limitations of study. The number of subjects we interviewed is relatively small. One reason for this is that during one visit, we discovered that another research team had arrived in the area a day earlier for a survey of kidney vendors. This team was having vendors brought to their base, and some were from *deras* we were scheduled to visit. Vendors who said that they had been "tested" by the "other doctors" were not interviewed. A second reason was the design of our study, which involved time-consuming drives to *deras* and dependence on community members for entry into sites. Nevertheless, given that we were looking for depth and richness rather than breadth of information, we believe we were able to achieve our objectives and gain important insights not reported before despite the small number of subjects.²¹ By the end of our third visit, we were recording repetitions in the themes that emerged from the subjects' narratives, suggesting that we were reaching a saturation point in the collection of information.

The other issue, discussed below, was the disconnect we found between our notion of privacy and what we encountered in the field. We discovered that *deras* represented a social "community," members of which often joined in the narratives of our subjects to offer their own comments and impressions. Our concern that this would influence some of the responses was allayed when we found that those interviewed in relative seclusion gave similar information, using identical phrases and idioms. An advantage of the "group encounters" was the opportunity to gauge the general ethos of the communities we met and the ways in which their members-vendors and nonvendors-related to one another. The lack of privacy, however, proved a hurdle in administering the SRQ to screen for anxiety and depression, and also in conversations held with some vendors' wives in the presence of their husband's family, especially the mother-in-law. Asking people to leave during our conversations with vendors would have been culturally inappropriate and might even have aroused suspicion, and asking people to leave during conversations with wives could have had bad consequences for them later.

Site and Demographic Data

Our interviews were conducted in *chaks*, clusters of houses and a few shops, or in *deras* consisting of the *zamindar's* lands with rooms for farm workers and their families. Access to many *deras* involved traversing dirt or gravel paths, sometimes on foot, through lush fields and or chards. Some of the rooms in which the laborers lived had neither electricity nor running water, in contrast to the *zamindars* well-built concrete residences. The hospitality with which vendors and their families met us was striking, as was their willingness to speak with us frankly. Charpoys (all purpose beds consisting of a wooden frame with jute ropes strung between the four sides) were placed under trees for us to sit on, and we were offered tea or water even in the poorest households. The only hostility we experienced came from a few *zamindars* who joined us as we were conducting interviews and wished to know who we were and why we were there. On the other hand, some *zamindars* requested that we visit their houses and examine them or their family members. Their presence would lead to a temporary pause in the vendors' narratives, to be

resumed once they left. All families in and around the *dera*, vendors and nonvendors alike, would converge upon us and pitch in with comments and additions to what was being related to us at the time. We found the notion of "privacy" of information to be an alien concept; we were in communities in which everybody seemed to know the details of each other's families and experiences, including the amount of money promised, and received, for a kidney. People filled in the details of each others' stories and sometimes prompted one another about dates and months of surgery and even the ages of their children. Our interactions with vendors and their families often ended up being "group encounters." When we met vendors and families within the confines of their rooms, neighbors and friends would often walk in to see what was happening and sit on one of the charpoys to offer their own opinions about selling kidneys. To administer the SRQ, the extent of privacy we could manage in many cases was a move to the most distant *charpoy*.

Our attempts to take consent were generally met with uncomprehending looks, followed by protests that this was unnecessary and that they were glad that doctors from the "big city of Karachi" had traveled all that distance to speak with them. Nevertheless, after explaining the particulars of our study, all subjects were told that they were under no obligation to speak with us and were free to refuse. None did.

Demographic Data

We interviewed thirty-two vendors (one couple was interviewed twice), four of whom were female, with age range of nineteen to forty-two years. Except for three individuals who had attended school until grade four, the rest were illiterate. The majority, twenty five vendors, had sold a kidney within the last two years, and twenty seven had done so to a hospital in Rawalpindi run by a retired colonel of the Army. (See Table 1.)

Total vendors interviewed	32 (one couple interviewed twice)
Vendors less than 19 years old	2
Vendors 20 to 40 years old	27 (age unknown for 3)
Currently married	27
Illiterate	29 (grade five: 2, grade four: 1)
Number of children per family (range)	1-11
Time since vending	<ul style="list-style-type: none"> • <1 year: 18 • 1-3 years: 9 • >3 years: 5
Other vendors in extended family	<ul style="list-style-type: none"> • Yes: 16 <ul style="list-style-type: none"> ◦ 1 family member: 8 ◦ 2 family members: 6 ◦ >2 family members: 2 • None: 6 • Not established: 10
Vendors referred to physician for proteinuria and/or hematuria	3 (none presented for follow-up)
Vendors referred for psychiatric assessment (based on SRQ assessment of 20 vendors)	10 (none presented for follow-up)

All except two had sold a kidney to pay off debts owed to zamindars; a majority was either still in debt or had accumulated new debts. None reported receiving the total amount they had been promised, and almost all had to pay Rs. 10,000 to Rs. 20,000 to the middleman. (See Table 2.)

Average debt before vending	Rs. 130,000 (Range Rs. 45,000 to Rs. 200,000)
Average money promised for kidney	Rs. 160,000 (Range Rs. 80,000 to Rs. 175,000)
Average money received	Rs. 103,000 (Range Rs. 70,000 to Rs. 155,000)
Money paid to middlemen	Range Rs. 8,000 to Rs. 20,000
Status of debt after vending	<ul style="list-style-type: none"> • 17 persistent/reaccumulated • 13 paid • 2 not established

None of the vendors questioned directly, except one, would recommend selling a kidney to anyone else, including those who had managed to pay off their debts. Among the thirty-two vendors interviewed, three had elevated blood pressure readings or blood or protein in their urine-significant findings in anyone with one kidney. All were provided referral slips for a physician in Sargodha. Due to difficulties with privacy, administration of the SRQ was possible with only twenty vendors. Of these, ten (including one woman) had sufficiently high scores, or symptoms judged sufficiently worrying, to be referred to a psychiatrist in Sargodha. Of these ten vendors, two were considered to be possible suicidal risks, and one reported attempting suicide with sleeping pills. Based on our subsequent communications with Ali, our primary community contact, and the Sargodha physicians, we learned that none of the vendors we had referred for follow-up visited the physician or the psychiatrist. As we were concerned that the noncompliance might be due to the cost of travel, we made arrangements, through Ali, to rent a van for them, but this, too, failed. Those that Ali managed to contact were either unwilling or afraid to ask the *zamin*.

Vendor Narratives and Conversations

Through open-ended questions about vendors' perceptions of lives after selling a kidney, several overlapping patterns of symptoms and changes in "self image" could be identified. Many were psychosomatic in nature.

Issues related to the incision. All vendors, including those with a nephrectomy done over three years ago, complained of symptoms related to their surgical incision (pain, spasms, pricking), even though an examination revealed well-healed surgical scars. One vendor was still afraid *tankey na tut jan* (that the surgical stitches would break). Many also complained of tiredness, generalized *kamzori* (weakness), *chukkar* (dizziness), and shortness of breath while working. All expressed an inability to work as hard as before, a perception confirmed by family members with whom we spoke. One vendor explained his tiredness by saying that *jism may khoon nahin hay* (my body has no blood in it). A common complaint was *hun wazan uthanay day naal dard* (lifting anything heavy now gives me pain), a significant issue.

The "half" man syndrome. A second cluster identified-and related to the left flank surgical scar-was a heightened sensitivity to or constant awareness of the left half of their bodies. Many vendors described

pain, numbness, or a burning sensation in the left arm and shoulder or the left side of the abdomen. Some also had left-sided headaches. With these symptoms came a sense of emptiness. Pointing to the left half of his body, one vendor told us that *mehsoos hota hay kay khalee jaga hay* (I feel that there is an empty space here), and that he was now an *adhoora banda* (incomplete or half a man). This curious sense of feeling "half," being "empty," somehow having been transformed into an "incomplete" person, was among the most common statements we heard. One young man pointed to the uncapped pen in a researcher's hand and said that he was now *adha* (half) like that pen; replacing the cap back on the pen, he said he was "like that" before surgery.

One vendor said that following the nephrectomy, his *mardani taqat kum ho gayee* (sexual potency has decreased). In another case, a mother told us that by selling his kidney, her son had *zulm kitta* (done injustice) both to himself and to her, as she had wanted grandchildren and thought she might not get them now. The belief that losing a kidney somehow makes a person incomplete, lessens a man's sexual power, and reduces a woman's childbearing capacity was also reportedly expressed by some family donors in an earlier study conducted in Pakistan.

Fears About the Remaining Kidney. Another related cluster of complaints revolved around profound anxiety? Persistent *khof & fikr* (fear and concern)-at being left with one kidney. Different phrases were used-*dil pay bojh* (weight on my heart), *chaubees ghanay fikr kay hun ikon gurda*, *maira saath kee hoyay ga* (I worry twenty four hours that I have only one kidney, what will happen to me), *dil ghabaranda* (my heart is restless, not at peace), and following nephrectomy *hun himmat nahin rae* (I have no strength/will left). One man said that if someone *uchi awaz nal bolay* (speaks to me in a loud voice) he became terrified, adding that *fikr say adha kay ikon gurda* (fear that I have only one kidney has made me half the man I was).

Two individuals used interesting ways to express the changes they felt in themselves and the sense of vulnerability connected to having one kidney. One said that *pehlan tees meter dee chalang Uganda san, hun sochna parda ay* (before I could leap across thirty meters, but now I have to pause/think about it). Another described himself before and after he had sold a kidney-*pehlan mein sher san, hun mein bakri an* (before I was like a lion, now I am like a she-goat).

A sense of hopelessness. Fifty percent of those administered the SRQ revealed profound levels of anxiety and a sense of hopelessness about life. Although we had no means of assessing their status before the nephrectomy, vendors perceived these feelings as originating following it. An intelligent, middle-aged vendor named *Chachu* (paternal uncle) made an insightful observation. He said that those who sell kidneys *zehan tay ten shun laga lainday hein; nafsiatee asar bohat honda ay* (suffer from tension in their minds; there is a great psychological effect on them), and this was why he never let it enter his mind. Others reported insomnia, crying spells, loss of appetite, and a lack of *sakoon* (peace) in life. Many said that *dil na lagda* (my heart is not into anything) and that they *muk gaya* (were finished/destroyed).

One man who sold his kidney without informing his wife-who said she would have stopped him, informed us that he felt *hun zindagee dee koi lor nahin; na wajood raya na sihat* (now I have no need for life; I have neither my body left nor my health). He added that *kam nahin honda, mein baikar ho gaya hun* (I cannot do any work, I have become completely useless). Another vendor who had been unsuccessful in clearing his debts sat staring into space and used the frequently voiced word *baikar* (useless) for himself. He said that *marnay ko dil chahda ay* (my heart feels that I should die) and that he no longer experienced any *khushie kay lumhat* (moments of happiness/pleasure) in his life.

Feelings of regret. One female vendor, an assertive young woman, told us she did not regret selling her kidney and added that "what is done is done." Such comments were exceptions, however; more commonly we heard words, even from those who had paid off their debts, such as *afsos* (deep sadness,

feeling sorry) and *pachtana* (regret, remorse) at the act. Different but overlapping reasons were given for this. One set related to the fact that despite selling a kidney and incurring the perceived harm, they remained under debt. A common statement was *gurda bhee gaya toy poora faeda bhee na hoya* (my kidney is gone and yet I have not reaped the benefit I wanted). Others stated that *qarza tay utarjanda kisee taranh, par gurda na baichna chahda see* (the debt could have been paid off somehow, but I should not have sold my kidney).

Some subjects expressed remorse connected to a religiously grounded perception that there was an intrinsic "wrongness" in selling an organ. One man described the kidney as a *naimat* (blessing) from God, and others said that selling a kidney was *Allah tala kaa gunnah* (sin in the eyes of Allah), a *buraee* (wrong, evil act), or *accha kaam nahin* (not a right/good act). One vendor described the money obtained from selling a kidney as *haram* (something strictly forbidden in Islam). We interviewed one man in our car by the side of the road, where he worked in a gas station (in addition to the work on a *zamindars* lands) to try and pay off his persisting loans. He wept as he spoke of his sense of hopelessness and said that he thinks of God all the time and asks for His help.

Two vendors among those we interviewed expressed feelings of profound shame at having sold a kidney and had concealed the act from various members of their families. One of them had told his wife that he had surgery for a kidney stone and was convinced that she would leave him if she discovered the truth. He had also not told his parents, for fear that the *biradari* (extended family) would find out, and he was miserable because *sub say dhoka kiya hay* (I have deceived everybody). In the case of the second vendor, his large extended family blamed his wife's influence on him and openly expressed their animosity toward her when she was present. The vendor himself was contrite that his act had resulted in shame for the entire family, and he added that people in the community made fun of those who sell kidneys.

Those we questioned directly said that they would not recommend that anyone sell a kidney. In answer to our query as to why they had themselves sold a kidney, the most common words they used were *majboori* (a word that arises from the root *jabr*, which means a state that is beyond one's control) and *ghurbat* (extreme poverty). One man expressed anger at his younger, unmarried brother, who had also sold a kidney despite his advice that *das saal zalil ho ja par gurdana day* (even if you have to suffer humiliation for ten years, do not give your kidney). He said that he had done it for the sake of his children and added—perhaps as a salve to his conscience—that at least he had "not killed anyone." Another vendor's advice to others was that *bhookay raho, gurda na do* (stay hungry if you have to, do not give your kidney), and a female vendor compared selling a kidney to *apnee nilami* (auctioning herself).

Feelings toward hospitals, physicians, and recipients. Although we asked no direct questions on this issue, some vendors offered unsolicited opinions about the hospitals and physicians involved in transplantations. One woman said that the doctors in the hospital where her husband sold his kidney were "nice," but the usual comments tended to be quite harsh. Except for three individuals, none had returned to the hospitals for follow-up. One man bitterly described the hospital as *sub karobar hay* (it is all a business) and said he would never return. He characterized those connected to the hospital as *kasaae* (butchers) and said he hated the place because *sub jhootay hein* (they are all liars). Some said that the hospitals were too far away and the cost of the fare beyond their means.

A sense of being victimized and deceived by the medical profession was expressed in general terms, and none knew the name of the surgeon or other physicians in the hospital. (All, however, were familiar with the names of middlemen.) Hospitals and staff were described variously as *sub choree da kaam ay* (in a business of theft), *sub daqa shahi ain* (all are the kings of thieves), *dhokay baz* (those who deceive others) and destroy lives like *phansee ka phanda* (a noose for hanging people). One female vendor described her experience in the hospital as one in which they *khoon choos Una; murda bana kayghar bhaj dain day hein* (sucked out all my blood; they send us home after turning us into corpses).

We detected little curiosity, or sympathy, toward the recipients. Vendors who managed to meet recipients in the hospital did so with the expectation of getting additional money and were disappointed and angry when this did not happen. In one *dera*, a young man casually mentioned that the "Arabi" (word for people from the Middle East) who had gotten his kidney died four days later. When another said that his kidney, too, had gone to an Arabi, a man in the group remarked "but they managed to save this old man and he didn't die." This was followed by loud laughter from everybody. This indifference and even disdain toward recipients contrasts with the emotional and psychological connection that altruistic donors often say they have with the recipients of their kidneys. To the vendors, the recipients of kidneys were affluent and often faceless strangers who had bought an important part of their bodies, often for less money than was promised.

Conversations in the Zanana

We met separately with some of the wives and female family members of male vendors. The women were friendly, curious about us, and very willing to speak with us. All of them had noticed that their husbands were quieter now and had less capacity for physical work. Their responses included anger and frustration, but also sympathy and concern for their husbands. Our most detailed encounter took place in the *zanana* (living area for women) of one *dera*, where we met the wives of three brothers who were all vendors. This was a small, one-door room that was furnished with two bare *charpoys* and rapidly filled with women and children, relatives, and neighbors, all crowding onto the *charpoys* with us.

Razia's husband had sold his kidney in 2005, but she said that they were still in debt. She added that her husband had not told her about his decision to sell a kidney, or she would have tried to stop him. The couple has two living sons and a four-year old daughter, but Razia has had seven miscarriages, all handled at home by the local *dai* (midwife). A large part of the money from the sale of her husband's kidney had been spent for these expenses and the births of her children. She lifted her shirt to show us a small bandage saying that she had just had emergency surgery without which the doctor had said she would die. She told us that they now also owed the surgeon Rs. 12,000.

Razia said that before his surgery her husband *khush rehnda, hun chup, chup ay. Bus pay rehnda tay sochda rehnda ay* (used to be a happy man, but now he is very quiet. He just lies around; he is always thinking). He was no longer able to work like before, and when he did not work she fought with him (said with a laugh in which the other women joined). Razia added that he was in pain, could not sleep, and often walked around at night.

Shehnaz, the wife of another brother and married at the age of fifteen, had also not known about her husband's nephrectomy until after it had happened, and she, too, was unhappy that he had undergone it. Shehnaz said that he used to be a happy and talkative man but had now become very quiet. He was always worried about what would happen to the family if he died. Shehnaz said, "When he says this I tell him that if he dies I will die with him."

In another *dera*, we spoke with a smiling, plump woman married to her cousin, who had sold his kidney. She said that since the surgery, her husband was quick to get angry with his children, but that he apologized afterward. As they were still in debt, she said that she was thinking of selling her kidney, too, but that her husband was not ready for her to do so. Another woman also reported that her husband became much angrier now, could not work as hard, and worried constantly that his remaining kidney would stop functioning. She poignantly described her husband by saying *oda wajood dard karda ay* (his entire being hurts now). Another vendor's wife, heavily pregnant, described her husband as *banda kaam da na reya* (the man has become useless; he can do no work), adding that it would have been better to stay hungry than to sell a kidney.

We spoke with *Chachu*, a middle aged kidney vendor, and his wife Bibi in a *dera* while sitting on *charpoy*s and sharing the shade of a tree with several black buffaloes tethered close by. *Chachu* had paid off his debts by selling his kidney and a cow. He now worked on *dehari* (daily wages), and Bibi was employed as a domestic servant in the household of a zamindar. Bibi, who was sitting close to one of us, offered her views *sotto voce* while Chachu was being interviewed. She said they were no longer in debt, but that Chachu *pehlay hor banda see, hun hor ay* (was a different man previously, and is now a different man), that he was now *adha* (half). She said selling a kidney is not a good thing but *majboor see* (they had no choice) as they wanted to free their children from the zamindar. Bibi said that before he sold his kidney, *Chachu* used to smoke a *hookah* occasionally but had now become a chain smoker.

Boota and His Family: A Case Study

We have chosen to present the story of Boota and his wife Nazeeran, whom we met twice, constructed through our field notes. To us this couple presents a microcosm of the experiential realities shared by so many others we met, snared in the ebb and rise of a tide of unending debt, inexorably sucking in other members of the family, vendors and others alike, in different ways. Their story also highlights the complete control of zamindars over the lives of vendors and their families, succinctly expressed in the words of a vendor when he said *apna kuch nahin hay* (there is nothing that is ours).

June visit When we first reached Boota and Nazeeran's *dera*, the *zamindar* had expressed reluctance to our meeting them, telling Ali (as we waited in the car) that "there is nothing wrong with them; they do not need to be seen by any doctors." Ali, who knows the *zamindar*, had tried to "soften him up" and suggested that we try again the next day. On that visit, the *zamindar* was nowhere in sight, and Ali led us to the little room where the family lives. Later, while we were speaking with Boota and his wife Nazeeran, Ali suddenly left the room. He told us on the drive back that he had seen the *zamindar* walking up and had gone over to keep him busy in conversation until we completed our interviews.

The room in which Boota and Nazeeran live with their six sons and two unmarried daughters (three other daughters are married) was reached by walking along a dusty dirt track leading away from the main residence. We walked past a water trough for cattle and saw several black buffaloes belonging to the *zamindar* tethered under a tree outside Boota's room. The only furniture in the small, windowless room with one door consisted of three bare *charpoy*s laid out parallel to one another, with one piled with a jumble of clothes. A wooden shelf on the wall facing the door was lined with what appeared to be the family's pots and pans. In the height of summer in Punjab, a small portable fan whirred in a corner, battling ineffectively against the heat and swarms of flies that buzzed around the sparse, dingy room. Outside the door, in the distance, we could see the *zamindar*'s acres of lush green fields and his orchards, the trees heavy with ripening fruit.

Boota and his wife welcomed us into the room with smiles and ushered us to one of the *charpoy*s. Nazi ran sat down on the *charpoy* facing us, while Boota squatted on the floor near the door. Their oldest, married son (not the vendor) and a silent, unmarried young daughter took their place on the third *charpoy* in the shadows behind us. The second son-unmarried and twenty-seven years old, who had also sold a kidney-was away at work, and we did not get to meet him. Throughout our conversation, in which the married son sometimes participated, shabbily dressed, barefoot children of different ages drifted in and out of the room. Our efforts to get the "consent" of the family were met with protests from Boota and Nazeeran; they said they were so pleased that we had traveled all the way from Karachi just to talk with them, there was no need to ask their *ijazat* (permission) as we were their *mehman* (guests). There were repeated offers of tea from Boota that he said he would make with the fresh milk of the buffaloes tied outside the room. When we declined politely, he offered to dilute the milk with water to make it digestible for our (city) stomachs.

Boota was a thin, gray-haired, quiet man who looked worn out and older than the age ("approximately forty") he gave us. Nazeeran (who did not know her age) was stockily built and talkative. Both were illiterate. Boota said that they had sold their kidneys because they were in debt for Rs. 200,000 (approximately \$3,500) borrowed from the *zamindar*. Nazeeran said she was the first to sell her kidney, and that she did it about two years ago. She was accompanied by her second oldest son, who sold his kidney to the same hospital seven months later, and Boota had done the same about a year ago. Boota said he had been promised Rs. 104,000 for his kidney but had received only Rs. 70,000 and had to pay Rs. 10,000 to Khalid (the middleman). He said that he also had to travel to Rawalpindi at his own expense to get "tests." The son added that from the money, they also had to pay *jurmana* (penalty) to the *zamindar* for something one of his brothers had done. Boota said that they were still in debt, and the two buffaloes they had bought with the money obtained from selling kidneys had also died.

The couple's description of the kidney trade was identical to what we heard from other vendors. The system worked like a well-oiled machine built on a nexus of middlemen, small courts, and hospitals and staff. Boota, Nazeeran, and their son were first taken by Khalid to a *kutcheri* (a small court) near the Rawalpindi hospital for *kaghazat bananay day liyay* (making out papers). A man in the *kutcheri* asked them if they were giving their kidneys *khushee say* (happily), and "we said yes." They were asked to put a thumb print on a piece of paper, but they said they did not know what was written on it. *Shanakhtee* cards (identification cards for Pakistani citizens) were also made for them, but the hospital retained all the papers.

We asked if they had also "signed" any papers in the hospital. Boota said that he had put a thumbprint on a paper, adding that the man (he did not know whether he was a doctor) had said something to him about *maut aur hayat* (death and life); he could not recall exactly what was said. We learned that although "discharge slips" routinely list a hospital stay (for "nephrectomy done") of six to seven days, potential vendors often live in a hospital room for many days prior to surgery. Several were housed together in one room (there were separate rooms for males and females), and they slept on the floor until a recipient was found. The hospital provided food for this period, but the cost was deducted from the kidney money at the time of discharge.²³

Boota said his kidney was given to a man from Karachi, who told him that *aap kaa aur hamara khoon ub aik ho gaya* (your blood and mine are now the same), but he did not give Boota any money. (Nazeeran told us in a matter of fact voice that the woman who received her kidney had died four days after the operation.) Despite three kidney sales within two years, the family had been unable to pay off the debt to the landowner, so they continued to work for him. Boota was worried about how they would marry off two of their daughters. He complained of weakness of his left arm since surgery and said that he urinated with *kum* (less) pressure. (His urine dipstick screening revealed traces of blood and presence of protein.) Coming close to tears, he said that since selling his kidney he has been experiencing *baichaingee saray wajoodich* (restlessness in his entire body/being). He could not sleep well and said *khof lagda ay* (I feel afraid). When we asked what he was afraid of, his son said that Boota wakes up in the night screaming that *koi mein lay janda ay* (somebody is coming to take me away). Boota told us that he prays to *Khuda* (God) that *behtar kay mein marjawan* (it is better that I die).

Nazeeran wept on and off during the interview. She mentioned general physical complaints-she felt *kamzor* (weak) all the time, had pain in the incision site and all over her body, and suffered from "gas" (bloating). When questioned about the kidney sale, she said the debt still remained, so *keefaida hoyay* (what was the benefit)? She also said that when she sold her kidney, it was as if *apni nilamee kittee* (I auctioned myself). Like many other vendors, Nazeeran said that *assan log udhay log an* (we are like "half" people), and *hun zindagee dee kee lor ay* (now what is the need/use of living)? When we inquired if she had ever contemplated suicide, she wiped her eyes with her *dupatta* (long scarf that covers the head

and chest), saying *majboori ay, zinda toy rehna ay* (I have no choice, I have to live), a reference to the fact that suicide is a grave sin in Islam.

Nazeeran vividly described her experience in the hospital and appeared to be suffering from flashbacks. She said that during her hospitalization, she had observed many other vendors after they had undergone surgery, and she described them as *pharaktay* (trembling/tossing/turning from side to side) in their beds, and said that she often woke up terrified that she was about to have surgery. The son confirmed that both his parents had insomnia, and he had occasionally come across them weeping at night. In view of the parents' bad experiences, we inquired why a son (brother of the son speaking with us) had also decided to sell his kidney. The son who was present responded that it was because of *mai-baap da zor* (pressure from the parents). He added that as they were still in debt, the family was considering that he also sell his kidney; the parents did not refute his statement.

As Boota's urine was abnormal and his SRQ score 11, we gave him referral slips and impressed upon him the importance of seeing the physician and the psychiatrist. He promised that he would do so. Nazeeran's urine screen was normal and her SRQ was 14, and although we did not refer her, in retrospect we believe that she, too, would have benefited from a referral to the psychiatrist. As we drove away, we asked Ali if he knew Boota and his family. He said that he knew them well, that they were in debt but they tended to "exaggerate." He thought that their current debt was probably about half of what they had told us and that he was aware that the others in the family were under pressure to sell a kidney.

November visit Ali had to teach classes in his college during our second visit to Boota and Nazeeran, so our contact person was a young vendor named Raza who seemed to have taken a liking to us. An illiterate but articulate and bright man in his early twenties, a bit of a nihilist and a cynic, he has involved us in lively discussions on what he considers to be the "meaninglessness" of life. Raza said he knew a family of vendors and directed the driver to the Sahab Town *dera*, which included the elaborate house of a *zamindar*. Situated across a narrow dirt road in front of the house was the rest of the *dera*-a straight row of half a dozen small rooms for the *zamindars* workers that opened onto a dusty, common courtyard with a few scraggly trees. Raza led us to a covered area in front of the *zamindars* residence, and the ubiquitous *charpoy*s appeared out of nowhere. We watched a thin, gray-haired man walk across the dirt road from the workers' quarters to where we sat, and much to our surprise, it turned out to be Boota. He was soon joined by Nazeeran, and both greeted us like long-lost friends. Almost immediately, Boota began to insist that we have tea with them, reminding us that we had not done so in our last meeting.

While we spoke with the couple, Raza left to see if he could locate the son who had sold a kidney (he did not appear this time, either). We learned that since June, no other member of the family had sold a kidney. We thought Boota and Nazeeran looked less anxious and teary-eyed than the last time, although on questioning they repeated some of their previous symptoms. They told us that they were still under a debt of Rs. 200,000 but were now working for a "nicer" *zamindar*. We asked how they had managed to convince the previous *zamindar* (from whom they had taken the loan) to allow them to leave his employment for that of another. Boota said that *Haji*, their present *zamindar*, had "bought" the debt from the last one, and so the family had moved to *Haji's dera* four months ago. We asked if Boota had gone to see the doctors as we had recommended. Nazeeran said that the *zamindar* had refused to give them time off, so they could not go to Sargodha. Boota was still spilling protein in his urine when we checked, and so we again lectured him about the importance of follow-up. We also gave a referral slip to Nazeeran for a psychiatrist, coupling it with a similar lecture, but were pessimistic about either of them following through on our advice.

Suddenly we heard a commotion and shouts from the direction of the workers' quarters. Boota and his wife sprang up and ran across the dirt road. We asked what seemed to be the problem and were told that their daughter Maqsooda was having a *dora* (the colloquial term for an epileptic fit) again. This young

woman had earlier been sitting quietly in the enclosure where we were speaking to her parents, but had then walked away. Together with Raza we hurried across the dirt road and saw Maqsooda, a good-looking young woman perhaps in her late teens, lying supine on a bare *charpoy* in front of one of the rooms. She was surrounded by a crowd that included men, women, and wide-eyed children. Her eyes were closed and several women were holding her arms firmly pinned down as she writhed and twisted and turned her body from side to side. Boota was at the foot of the bed holding on to her legs and at the same time trying to pull down her shirt to cover her lower abdomen and thighs. We heard him say, "*Maqsooda, Kalamaparh, bus Kalamaparh* (recite the Kalama [a verse in the Quran])," and this refrain was taken up by others in the crowd.

As we walked up, we saw Maqsooda's lips moving and her eyelids beginning to flutter. We were confident that we were not witnessing a seizure of any kind. One of our team members (a female) told the women to let go of Maqsooda and the crowd to move back, then sat down next to her and asked her to open her eyes. "I am a doctor, and I have very good medicine that will make you feel better." Maqsooda opened her eyes and watched as we checked her pulse and examined her. We asked if she was hurting anywhere, and she silently pointed to her left flank (the site of her parents' incision sites). Boota said that Maqsooda had been having "pain in her kidney" and frequent *doras* such as the one we had just witnessed. On examination, we could detect no physical abnormalities, and we were convinced that what we had just observed was a display of conversion reaction symptoms manifesting as a seizure.²⁴

By the time we had her swallow a paracetamol (analgesic) tablet, Maqsooda was smiling, sitting up on the *charpoy*, and ready to talk. We reassured her that there was nothing wrong with her kidney and suggested that perhaps she was just tired. Maqsooda told us that she worked all day for the *zamindar* (a young man with a wife and one young child), washing dishes and cleaning the house. Boota added that she often returned home very late at night, a fact that did not seem to perturb him or Nazeeran. To diffuse the situation further, we asked if people wanted us to take their photographs. The family and all the members of the *dera* milling around now clustered around a smiling Maqsooda. Laughing children clambered up onto her *charpoy* for the picture taking session.

The Vendor and Beyond

The vendors we met are among the most socioeconomically disadvantaged citizens of Pakistan, and in almost all cases had sold a kidney to pay off debts. Following the nephrectomy, almost all of them reported perceptions of significant deterioration in their physical health and an inability to work as hard as before, even as they mostly failed to escape the cycle of crushing debt. Similar findings have been reported in the handful of studies undertaken on paid, unrelated "donors" in India and Iran.²⁵ Our screening also revealed significant psychological repercussions, commonly expressed as a sense of profound hopelessness, a perception of the self as somehow halved and incomplete following the nephrectomy, and constant anxiety for the remaining kidney. The family members we spoke with, including the wives, confirmed the vendors' physical and psychological deterioration.

This contrasts with findings in an earlier, comprehensive study of family members in Pakistan who donate kidneys to kin. Within the norms of closely knit extended families, kidney donation was motivated by love for a family member, to fulfill religious obligations to help your own "blood" (which is rewarded by God), and to protect the socioeconomic future of profoundly interdependent extended families. Many donors reported heightened self-esteem and an increase in their stature within the family.²⁶

An important aspect of our research on kidney vendors in Pakistan is that our empirical data suggests selling a kidney carries negative social, psychological, and emotional ramifications that extend far beyond the vendor to the immediate and extended family and also to the community. In this light, the arguments for organ markets as merely a transaction between two freestanding biological entities exercising their autonomy, seemingly in a vacuum, can be reductive and misleading. Through our time spent with vendors

in the *deras* of Sargodha, and through their generosity and willingness to speak with us frankly, we were able to glimpse firsthand the realities on the ground of personal and collective existences, hopes, and disappointments, their "current pressures and uncertain prospects," and the ways in which many lives are engulfed when a family member sells a kidney.²⁷ Through our observations and through informal conversations with others we met, we were also able to observe subtle shifts in the values of communities involved in organ vending, and-most disturbing to us-we could see how these practices serve to modify opinions about the integrity of medical professionals.

The vendor When laborers in Punjab sell a kidney, they do so not on the strength of philosophical positions on ownership of or property rights to their bodies, or in order to exercise their freedom to make autonomous choices-the issues that form the core of international debates among ethicists, physicians, and economists. In the words of the vendors, they sell a kidney because of *majboori*-a word meaning lack of options, a situation over which one has no control-in order to fulfill what they see as obligations toward immediate and extended families in which they are inextricably embedded, and within systems of social and economic inequalities they can neither control nor escape. They sell kidneys in hopes of paying off loans taken to cover their families' medical expenses or to meet their responsibilities for arranging marriages and burying their dead. These are recurring expenses, and for most the debts rapidly accumulate again, even if they have been partially or completely paid back with the money from selling a kidney. Some sell kidneys in the hope that by paying off their loans to the *zamindar*, they can free their children from his employment and enable them to work on daily wages. Most are not only unsuccessful in freeing themselves from debt but are left in a worse situation because of the terrible price they pay in terms of their health.

The obvious paradox is that, despite these known consequences and although none said they would recommend that anyone sell a kidney, we met several families in which more than one member had sold a kidney. Perhaps the answer to this riddle lies in the dynamics of power structures and inequalities described by psychologists, historians, and political scientists, in which the psyche of the oppressed and the behavior of the oppressor perpetuate the cycle of oppression.²⁸ The families we met, engrossed in a struggle to survive from one day to the next, had little time left for imagining a "future" that includes the consequences of selling a kidney. This situation is compounded by a system in which *zamindars* exercise complete control over the time, mobility, and physical space of the workers. This was expressed succinctly by one vendor when he said *apna kuch nahin hay* (there is nothing that is ours).

The state of poverty and the restrictions imposed by the *zamindars*, which we witnessed repeatedly as we moved between *deras*, effectively limit the ability of the laborers even to imagine, let alone undertake, alternatives to selling a kidney to pay off debts or even to pursue medical help. Within these realities, the argument that preventing impoverished people from selling a kidney "ignore [s] the fundamental tenet of Western society-that people be allowed to control their own destiny"?appears parochial and cavalier.²⁹ And arguments that trumpet the "autonomy" of the impoverished to sell organs and equate it to the right "each of us" has to "engage in risky behaviors" such as "sky diving, volunteering for military service . . . and smoking cigarettes" seem cynical and out of touch with reality.³⁰

The family, and kidneys as commodity Our study also reveals how the vortex of poverty and debt sucks in others in the family beyond the vendor. Persisting debts lead to some times subtle, sometimes overt, pressure on others to sell a kidney. The resulting anxiety and guilt manifests in different ways, as demonstrated by the conversion reaction seizures we observed in Boota's daughter. These pressures were also evident in our meeting with Ahmed, the husband of a vendor. A slight man with noticeable tremors of his hands, he sat quietly as we interviewed his wife. Afterward, Ahmed said he had not been feeling well lately and asked us to examine him. He complained of pain all over his body, general weakness, and insomnia. He said that a doctor had told him after listening to his heart and lungs that his *gurday kharab hein* (kidneys are diseased/not working). Our detailed history and examination revealed nothing

abnormal, but Ali told us later that Ahmed was being pressured to sell a kidney as the family still owed money to the *zamindar*.

Renee Fox and Judith Swazey, well known for their sociological, ethnographic study of the inception and evolution of the organ transplantation scene in the United States, criticize what they see as the medical profession's transformation of organ transplantation into something "analogous to a commercial industry." They note that "increasingly, organs are being thought of as 'just organs' rather than as living parts of a person," and that this "biological reductionism" carries insidious implications for how we see ourselves and how we relate to others. According to Fox, there is a "progressive routinization and profanation of organ transplantation" as a result of the increasingly "commercialized view" of organ transplantation, a specialty that began in a sense of awe and wonder among its practitioners.³¹ Although they are commenting on highly educated transplantation professionals in the United States, we found some of their observations echoed in the way members of the illiterate rural communities of Punjab, driven by their dire circumstances, have come to see their bodies.

Among the farm laborers we met, living in regions where growing numbers of people have sold a kidney, there appears to be a resigned acceptance of the thought that their kidneys are a kind of commodity, the only material asset they possess in life, that can be sold to pay debts or cover expenses. For those inextricably snared by their lack of financial resources, selling a kidney has been "routinized" as an unpleasant but mundane act, and physicians are increasingly seen as organ purveyors complicit in this business. The latter perception, profoundly distressing to us, was brought home to us on different occasions during our field visits.

Once when we had stopped to admire flowering mustard fields on both sides of the road, we were approached by a man accompanied by his pregnant wife and three barefoot children. As his wife stood by silently, he told us that he had eight children and was under debt to his *zamindar*. Having learned from our driver that we were doctors, he asked us if we could make arrangements for him to sell a kidney to pay back the loan. On another occasion, while walking through the narrow alleys of a settlement in search of a vendor's house, we stopped to ask directions from a man selling vegetables from a small pushcart. After providing directions, the man said that he could see we were doctors and inquired if we could help his friend sell a kidney. We found these encounters deeply disturbing.

The Zamindars We also observed a curious phenomenon that we came to label "vicarious kidney anxiety" among some of the *zamindars* who had vendors in their employment. They often asked us to check them for abdominal and back pain, which they invariably related to problems with their kidneys. In one *dera*, the *zamindar* requested that we examine his mother, whom we met in a room full of female relatives who had all gathered to be seen by the "Karachi doctors." As soon as we entered, a ten-year-old boy asked us if we had come to check his kidneys, too, followed by a woman who inquired if we had brought "machines" to test their kidneys. Another woman in the room was convinced that the pain in her abdomen was related to her kidneys, despite an ultrasound report she showed us that revealed normal kidneys. Before leaving the *dera*, we were approached by the *zamindar's* cousin, who said his check-up in "a big hospital in Paris" was normal but that he was convinced his back pain was related to kidney disease. We had similar encounters with *zamindars* in other *deras*. The psychosomatic anxieties of the vendors seem to have seeped, as though through osmosis, into their employers.

The Community at Large

Throughout the study we also interacted informally with many people in the town of Sargodha and the areas in which the *deras* are located. Many were aware that laborers in the district sold their kidneys to private hospitals in cities and expressed mixed opinions about the vendors. Some considered the practice to be related to poverty and illiteracy of vendors- "they are too ignorant to know what they are doing to themselves." Some expressed anger at the government for not taking steps against poverty and leaving

villagers open to exploitation. But many were far less sympathetic and tended to look with disapproval and disdain upon vendors and their families. We were told that "these people waste the money" they receive from selling their kidneys by using it for cell phones, extravagant weddings, and large dinners celebrating circumcision ceremonies for their sons. A few also expressed resentment at the vendors and "foreign TV and news agencies" that came to the area to make documentaries that give Pakistan "a bad name."

The International Debates

Is this study, conducted in the remote *deras* and villages of Punjab, relevant to international debates on kidney commerce and regulated markets for organs? We believe it is. The presence of power differentials within societies based on economic and social status is a global issue, one that is on the increase both within and among countries. The communities of vendors we studied exist in a milieu that may be specific to Pakistan, but their lives, and the circumstances in which they live them, reflect an extreme example of the variations of economic disparities and social inequalities that are universal realities from which no country can now be considered entirely exempt.

All studies to date clearly indicate that it is the most disadvantaged and the most vulnerable in any society who resort to selling a kidney, and that they do so only when they are left with no other alternatives to feed their families, pay off debts, or get health care. When we consider whether to legalize some form of kidney commerce, then, we should not overlook the fact that it is always the poor and the disadvantaged who end up exercising a "right" or "freedom" to sell their kidneys. Margaret Lock has called attention to this problem: in her comments on the "crisis" of organ shortages and the debate about instituting organ markets in the United States, Lock criticizes market proponents for "studiously avoiding any discussions of inequities, dissent, and above all, the lived experience of those at center stage."³² To us, this reflects a failure of collective obligations toward the less fortunate and society's abnegation of responsibilities toward its most needy.

Although studies about social ramifications for those who sell a kidney are rare in academic literature, those that are available also reveal, as ours does, unequivocally poor outcomes for vendors.³³ Our study adds to this picture by providing insights into the psychosocial consequences of selling an organ that reach beyond the vendor, to the family and the community. The sale of a kidney by one family member can inevitably lead to subtle and not-so-subtle pressures on others to follow suit, and it carries with it the potential for the eventual stigmatization of individuals and of whole communities as organ "sellers." People always exist within families and communities, and it seems to us that our findings in the *deras* of Punjab would be equally pertinent, in varying degrees, to other societies. We believe that international discussions about organ commerce will remain reductive and shallow if they continue to be framed solely as transactions between two individuals, without taking into account the real possibility that there may be broader ramifications for families and societal ethos.

Equally important is that the Pakistani experience of kidney commerce over the last two decades confirms that the practice leads to the gradual erosion of altruistic donation. In the first several years following the initiation of kidney transplantation, the majority of organs in Pakistan were donated by family members driven by love and emotional connections with the patient. By the late 1990s, with the option of transplants with kidneys bought from unrelated donors, donation by family members dropped precipitously, as had also happened in other countries that introduced commerce in kidneys, including Iran, Israel, and Hong Kong.³⁴ In light of these experiences, we believe it is unrealistic to argue that certain societies would somehow remain immune to this phenomenon. As Gabriel Danovitch has written, organ vending "does not cohabit well with altruistic living donation."³⁵

Finally, in our opinion, Anglo American philosophical principles have exerted a disproportionate influence in discussions about organ markets. They have helped make a legalistic language, resting on

rules and regulations, the dominant way of thinking about those markets. American proponents of kidney markets have long promoted this procedure-oriented approach, but recently some commentators in developing countries have employed it as well. The central premise is that the buying and selling of organs can be made ethical through proper monitoring and regulation.³⁶ Alexander Capron, commenting on the connection of social science and American bioethics, states that "bioethics literature is more concerned with who may decide than the morality of the decision, more often framed in terms of one's right to do something than in terms of what is the right thing to do."³⁷ The observation is certainly apt for the arguments that support organ commerce and regulated organ markets.

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References

1. A.L. Friedman, "Payment for Living Organ Donation Should Be Legalized," *British Medical Journal* 333 (2006): 746-48; A.J. Matas and M. Schnitzler, "Payment for Living Donor (Vendor) Kidneys: A Cost Effectiveness Analysis," *American Journal of Transplantation* 4 (2004): 216-21; CA. Erin and J. Harris, "An Ethical Market in Human Organs," *Journal of Medical Ethics* 29 (2003): 137-38; M.M. Friedlaender, "The Right to Sell or Buy a Kidney: Are We Failing Our Patients?" *Lancet* 359 (2002): 971-73; E.A. Friedman and A.L. Friedman, "Payment for Donor Kidneys: Pros and Cons," *Kidney International* 69 (2006): 960-62; also see "Demand Soars on Kidney Transplant Market," *NewsMax.com Wires*, April 3, 2007, <http://archive.newsmax.com/archives/articles/2007/4/3/143617.shtml>, and "Your Part or Mine?" *Economist*, November 18, 2006, 65-66.
2. J. Radcliffe-Richards et al., "The Case for Allowing Kidney Sales," *Lancet* 351 (1998): 1950-52.
3. S.M. Rothman and D.J. Rothman, "The Hidden Cost of Organ Sale," *American Journal of Transplantation* 6 (2006): 1524-28; F.L. Delmonico et al., "Ethical Incentives-Not Payment?for Organ Donation," *New England Journal of Medicine* 346 (2002): 2002-5; G.M. Danovitch and A.B. Leichtman, "Kidney Vending: The 'Trojan Horse' of Organ Transplantation," *Clinical Journal of the American Society of Nephrology* 1 (2006): 1133-35.
4. For some examples from India, the Philippines, and China, see S.S. Chattopadhyay, "A Kidney Racket in West Bengal," *Frontline-20*, no. 15 (2003); "Discount Kidneys for Sale in Living Donor Hotspot," *Gulf News*, April 19, 2008; Y. Yun and J. Da, "Illegal Kidney Transplant in Mainland Hospital," *Epoch Times*, <http://en.epochtimes.com/news/6325/39692.html>.
5. Y Shimazona, "The State of the International Organ Trade: A Provisional Picture Based on Integration of Available Information," *WHO Bulletin*, <http://www.who.int/bulletin/volumes/85/12/06-039370/en/print/html>.
6. N. Scheper-Hughes, "The Global Traffic in Human Organs," *Current Anthropology* 41, no. 2 (2000): 191-211; also see N. Scheper-Hughes, "Keeping an Eye on the Global Traffic in Human Organs," *Lancet* 361 (2003): 1645-48.
7. A handful of surveys related to health and economic conditions of kidney sellers can be found in medical journals, but ethnographic studies involving in-depth interviews are a rarity. For examples of the former see M. Goyal et al., "Economic and Health Consequences of Selling a Kidney in India," *Journal of the American Medical Association* 288 (2002): 1589-93, and A.J. Ghods, S. Ossareh, and P. Khosravani, "Comparison of Some Socioeconomic Characteristics of Donors and Recipients in a Controlled Living Unrelated Donor Renal Transplantation Program," *Transplantation Proceedings* 33 (2001): 2626-27. The few academic publications about kidney vendors based on ethnographic field research include L. Cohen, "Where It Hurts: Indian Material for an Ethics of Organ Transplantation," *Daedalus* 128, no. 4 (1999): 135-66; J. Zargooshi, "Quality of Life of Iranian Kidney 'Donors,'" *Journal of Urology* 166 (2001): 1790-99, and J. Zargooshi, "Iranian Kidney Donors: Motivations and Relations with Recipients," *Journal of Urology* 165 (2001): 386-92.
8. S.A. Rizvi and S.A. Naqvi, "Kidney Transplantation in Pakistan," *Clinical Transplantation* (2000): 381-82; S.A. Naqvi, "Community Involvement in Increasing Transplant Activity," *Transplantation Proceedings* 31 (1999): 3280-81; F. Jawad et al., "Problems of Donor Selection in a Living, Related Renal Transplant Program," *Transplantation Proceedings* 30 (1998): 3643.
9. S.A.A. Naqvi et al., "A Socioeconomic Survey of Kidney Vendors in Pakistan," *Transplant International* 20 (2007): 934-39. This is a questionnaire-based study, the only one to be undertaken by a team of health care professionals in the country. In comparison, the national press and media have been very active in reporting

- news stories based on meetings and interviews with ven dors. See A. Mehdi, "Jobless Youths Offer Kidneys for Sale," Dawn, June 2, 2005; Z. Tahir, "Hundreds Deprived of Kidneys in Punjab," Dawn, May 27, 2007; A. Ansari, "Kidney Donor Has the Worst of Both Worlds," Dawn, July 10, 2007.
10. F. Moazam, *Bioethics and Organ Transplantation in a Muslim Society: A Study in Culture, Ethnography, and Religion, Bioethics and Humanities*, ed. E.M. Meslin and R.B. Miller (Bloomington: Indiana University Press, 2006), 28-30.
 11. C. Geertz, "Thick Description: Towards an Interpretive Theory of Culture," *The Interpretation of Cultures* (New York: Basic Books, 2000), 3-32.
 12. On September 4, 2007, after years of pressure, the government of Pakistan finally passed the Human Organs and Tissue Transplantation Ordinance, 2007. The ordinance requires all institutions, private and public, to register with and provide annual data to a national oversight committee, whose functions include periodic inspections of all transplant hospitals. See B.S. Syed, "Organs Trade Ordinance Issued," Dawn, September 4, 2007.
 13. F. Moazam, "Organ (ised) Crime," Dawn, magazine section, August 27, 2006. This article gives an overview of the Pakistan kidney trade and lists some of the Web sites of hospitals in Punjab advertising "transplant packages" for foreigners at that time.
 14. See Naqvi, "Socioeconomic Survey of Vendors," 936. Among the 239 vendors surveyed, kidneys from 69 percent were used to transplant non-Pakistanis. At the WHO Regional Consultation Meeting on Cell and Organ Transplantation held in Karachi in November 2005, nephrologist Nabil Mohsin presented data showing that following the drop in kidney tourism to India (with passage of the Indian Transplant Law in 1995) and then to Iraq (due to the Gulf war), patients from the Middle East were traveling increasingly to Pakistan for transplants; "Trend of Renal Transplant Operations-Living Related, Cadaver and Un related from Outside the Saudi Kingdom."
 15. "Surgeon Accused of Kidney Theft Still at Large," Dawn, July 8, 2006; "Kidney Theft Victim Seeks Compensation," Dawn, July 30, 2006.
 16. The Sindh Institute of Urology and Transplantation provides free care and has a good reputation. For a breakdown by provinces of kidney transplants done by SIUT, see M. Alam, "SIUT Set to Become Region's Biggest Transplant Center," Dawn, August 6, 2008. Of the 2,030 patient transplants done to date, 1,194 were from Sindh, 641 from Punjab, 127 from Balochistan, 57 from NWFP, and 11 from Azad Kashmir.
 17. P.R. Ulin et al., *Qualitative Methods: A Field Guide for Applied Research in Sexual and Reproductive Health* (Durham, N.C.: Family Health International, 2002), 59-61.
 18. Our primary contact was Ali, a young man born and raised in a *dera* near Sargodha and active in social work within local communities. A landowner who knew several vendors but employed none was also helpful. During our first visit to Sargodha we also contacted the Naib Nazim (deputy mayor) about our study due to safety concerns, as a few months earlier a member of our institution was assaulted while making inquiries about vendors. A general practitioner and a psychiatrist were also contacted for follow-up for vendors we judged to require medical attention.
 19. The study was carried out during three field visits in April, June, and November, with each visit lasting from four to five days. Our second visit was delayed twice. The first delay occurred when Ali called to say that the harvest season in Punjab was not over and that vendors would have difficulty taking time away from work. The second delay was due to the May 12 face-off between lawyers and the government in Karachi, leading to violence that spread to other provinces, including Punjab.
 20. For use of the SRQ in Pakistan, see K. Saeed, S.S. Mubashar, and I. Dogar, "Comparison of Self Reporting Questionnaire and Bradford Somatic Inventory as Screening Instruments for Psychiatric Morbidity in Community Settings in Pakistan," *Journal of College of Physicians and Surgeons of Pakistan* 11, no. 4 (2000): 229-31; D.B. Mumford et al., "Stress and Psychiatric Disorder in Rural Punjab: A Community Survey," *British Journal of Psychiatry* 170 (1997): 473-78; S. Ahmer, R.F. Faruqi, and A. Aijaz, "Psychiatric Rating Scales in Urdu: A Systematic Review," *BMC Psychiatry* 7 (2007): 59, <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2186345>.
 21. B. Glaser and A. Strauss, *The Discovery of Grounded Theory* (Chicago, 1990: Aldine Publishers, 1967).
 22. Moazam, *Bioethics and Organ Transplantation in a Muslim Society*, 164-67. Moazam's ethnographic research revealed that the reasons for reluctance to donate a kidney include a belief that the loss of one kidney somehow reduces an individual to *adha insan* (half a person). This "halfness" is believed to make one *kamzor* (weak) physically and sexually and make childbearing difficult for women. This is felt to be particularly problematic if the potential donor is unmarried, as it results in not getting an ideal "match" for marriage. In some cases, the fact that one has donated a kidney is not revealed to anyone beyond the immediate household.

23. This clarified a conversation we had had in Karachi with a man who said he was planning to have a transplant done in one of the Rawalpindi hospitals. He said the hospitals ran a "one-window operation": all you had to do was give a blood sample and they did the rest. According to him it was like a *gurda piri* (kidney market) there. The man was drawing an analogy to a *bakrapiri* (goat market), where there are milling herds of goats that may be purchased for sacrifice.
24. Diagnostic and Statistical Manual of Mental Disorders, 4th ed., text revision (Arlington, Va.: American Psychiatric Association, 2004), 492-98. The seizure variety of conversion disorders presents as voluntary motor or sensory symptoms, suggesting a neurological condition as a result of stress or conflicts being experienced by an individual. Conversion reactions are "a way of expressing distress but, unlike malingering, are not produced intentionally by the subject." This variety is "more commonly reported in rural populations, [and] individuals of lower socioeconomic status." DSM notes that "The form of the symptoms reflects local cultural ideas and acceptable ways of expressing distress."
25. For the lack of economic improvement following the sale of kidneys by Iranians, see P. Khajehdehi, "Living Non-Related versus Related Renal Transplantation-Its Relationship to the Social Status, Age and Gender of Recipients and Donors," *Nephrology, Dialysis, Transplantation* 14 (1999): 2621-24, and A. Griffin, "Kidneys on Demand," *British Medical Journal* 334 (2007): 502-5. Khajehdehi found that 87 percent of the living unrelated donors remained in "economic deadlock" due to debt, unemployment, illness, and drug abuse. Griffin offers a good overview of reports about the transplant system in Iran and notes that despite inconsistent data, what is "true" is that "nearly all the donors are desperately poor men who do not want to be identified" due to fear of social stigma. For studies about quality of life and psychosocial repercussions on those who have sold a kidney in Iran, see *Zargooshi*, "Quality of Life of Iranian Kidney 'Donors,'" and "Iranian Kidney Donors: Motivations and Relations with Recipients." For a report on Indian vendors, see Goyal et al., "Economic and Health Consequences of Selling a Kidney in India." A recent newspaper article reports an interview of 109 kidney vendors by the Philippine Society of Nephrology, revealing that "almost 80% of the villagers were just as poor as they were" before they sold a kidney. See J. Gomez, "Philippines: No Kidneys for Foreigners?" Associated Press, April 1, 2008.
26. See Moazam, *Bioethics and Organ Transplantation in a Muslim Society*, 137-145.
27. A. Kleinman, "Moral Experience and Ethical Reflection: Can Ethnography Reconcile Them? A Quandary for 'The New Bioethics,'" *Daedalus* 128, no. 4 (1999): 69-97.
28. For a landmark study on the economic conditions of laborers in rural Punjab, see M. Darling, *The Punjab Peasant in Prosperity and Debt* (Oxford, U.K.: Oxford University Press, 1925). For literature on the psychology of the oppressed in the context of male-female relationships, see J.B. Miller, *Toward a New Psychology of Women* (Boston, Mass.: Beacon Press, 1986).
29. A.J. Matas, "Should We Pay Donors to Increase the Supply of Organs for Transplantation? Yes," *British Medical Journal* 336 (2008): 1342-43.
30. Friedman and Friedman, "Payment for Donor Kidneys."
31. R.C. Fox and J. Swazey, *Spare Parts: Organ Replacement in American Society* (New York: Oxford University Press, 1992): 207-8; R.C. Fox, "Afterthoughts: Continuing Reflections on Organ Transplantation," *Organ Transplantation, Meanings and Realities*, ed. S. Younger, R.C. Fox, and L.J. O'Connell (Madison: University of Wisconsin Press, 1996), 252-72.
32. M. Lock, "Transcending Mortality: Organ Transplants and the Practice of Contradictions," *Medical Anthropology Quarterly*, New Series 9, no. 3 (1995): 390-93.
33. I. Sajjad et al., "Commercialization of Kidney Transplants: A Systemic Review of Outcomes in Recipients and Donors," *American Journal of Nephrology* 28 (2008): 744-54. In this literature search, the authors could find studies on vendor outcomes only from India, Pakistan, and Iran, all suggesting poor "medical, socioeconomic and emotional outcomes." Along the same lines, also see review article by V. Jha and K.S. Chugh, "The Case against a Regulated System of Living Kidney Sales," <http://www.medscape.com/viewarticle/543585>.
34. Danovitch and Leichtman, "Kidney Vending."
35. G.M. Danovitch, "Cultural Barriers to Kidney Transplantation: A New Frontier," *Transplantation* 84, no. 4 (2007): 462-63.
36. L.D. de Castro, "Commodification and Exploitation: Arguments in Favor of Compensated Organ Donation," *Journal of Medical Ethics* 29 (2003): 142-46. Castro, who is from the Philippines, argues for a market that "will freely determine the price of human organs in a market economy" that can, among other things, "monitor developments," "protect donors" against middle men, and ensure that "organs are sourced legitimately." Also

see A. Bagheri, "Compensated Kidney Donation: An Ethical Review of the Iranian Model," *Kennedy Institute of Ethics Journal* 16. no. 3 (2006): 269-82.

37. A.M. Capron, "What Contributions Have Social Science and the Law Made to the Development of Policy on Bioethics?"

Farhat Moazam, "Ethical and social dimensions of brain death," *Pakistan Journal of Neurological Science*, vol. 1, no.1, (2006): 39–41.

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Ethical and Social Dimensions of Brain Death

Farhat Moazam

"The medicalization of society has brought the epoch of natural death to an end Technical death has won its victory over dying"

Ivan Illich (d. 2002)ⁱ

Traditionally, the death and the dying of an individual was not a "practical" or medical issue but an event associated with profound spiritual, religious and social symbolism. It was considered a natural event or a call from God, the moment when the last breath was drawn, the heart stopped beating, and the spirit or soul departed the body. But with the advance of medical science, and as perceived through the biological prism of the medical profession, death has gradually acquired a new persona, one which Illich labels the "clinical death." The concept of whole brain death is a good example of the kind of death that Illich alludes to.

In this essay I will focus on the historical events that led to the introduction and acceptance of the clinical criterion for death - whole brain death - in the 1970s, and some of the theological and philosophical concerns expressed at that time regarding this concept. I will also provide a brief synopsis of the academic debate on this issue that continues to this day, and mention existing pockets of resistance despite the wide acceptance by healthcare professionals of the irreversible loss of brain function as a clinical and legal criterion for determination of death.

Prior to 1970 the only criterion used to pronounce death in a patient was the irreversible cessation of cardiopulmonary function. In 1968 a debate ensued in the United States about a "new definition of death" that was proposed for medical and legal usage. The stimulus for this was an influential article published in JAMA and authored by an Ad Hoc Committee of the Harvard Medical School.ⁱⁱ The Ad Hoc Committee recommended the use of whole brain death criterion to pronounce as dead those deeply comatose patients who were medically judged to have suffered irreversible loss of all integrating capacity of their brains. The reasons underlying the recommendation that this set of criterion be added to the traditional criterion of cardiopulmonary arrest were primarily utilitarian and pragmatic in nature.

The first of these was a result of the increasing availability of mechanical ventilation. This made it possible to keep the heart beating for days in irreversibly comatose patients considered to have a predictably dismal outcome, and in whom there was certainty that cardiac function would cease with discontinuation of mechanical respiration. But such patients, "alive" in light of established cardiopulmonary arrest criterion, could not be disconnected from ventilators without legal repercussions for physicians; they had to be pronounced "dead" by some other criterion. The second, and equally important, reason for introducing whole brain death criterion was the rapidly advancing field of organ transplantation. These patients provided an excellent source for procuring organs that could be transplanted into patients who had no other hope of survival. Legal acceptance of the whole brain death

criterion would thus side step the existing Dead Donor Rule that specified that a patient neither be alive when the organs are removed, nor killed by the process of removing them.

Among the first scholars to express moral discomfort about whole brain death recommendations were the Christian theologian Paul Ramsey and philosopher Hans Jonas. Both were members of the Task Force on Death and Dying instituted by one of the first and newly established bioethics centers in the State of NY, the Hastings Center. Ramsey took a pragmatic approach; he endorsed the proposed criterion but did so with a warning. He pointed out that there was a moral confusion of two opposing things inherent in the proposal – that between “the determination of when to break off sustaining medical interventions” and the fact that this in itself presupposes “that the patient is still alive.” His other concern dealt with the danger of conflating the death of one patient with another patient’s need for an organ transplant.ⁱⁱⁱ Ramsey, calling these the “twin perils,” recommended that these two considerations must be kept separate and never considered together. He nevertheless characterized the new criterion as bringing about a “sea-change in the attitude towards death.”

Jonas on the other hand had more serious reservations. His major concern was that legitimizing the use of brain death criterion would serve to “open the road” to a rush for harvesting organs for transplantation. It would allow keeping a person in a state of “life by the older definition” primarily in order to “get his organs and tissues under the ideal condition of what would previously have been ‘vivisection’”. He predicted strong medical pressures for this to happen if the proposal was accepted. His discomfort was also rooted in his belief that “we do not know the exact borderline between life and death.” To Jonas, the new definition of death should be authorized “only to break off a sustaining intervention [cardiopulmonary life support] and let things take their course” and never as means of sustaining patients until tissue and organs could be harvested.^{iv}

The issue of using brain death criterion to pronounce death, and its permissibility within *Shari’a*, was also discussed at some length by Muslim scholars and jurists albeit at a later date. In 1986 the Academy of Islamic Jurisprudence held an international conference in Jordan dedicated to this issue. Participants included *ulema* and *fuqaha* as well as many Muslim physicians from several countries. The final recommendations of the Academy included “unanimous” approval of whole brain death criterion and its permissibility within Islam. Ebrahim Moosa’s analysis of the details of the proceedings however provides interesting insight into the discussions of the participants, and opinions that were hardly unanimous. Muslim physicians understandably spoke with one voice in their approval of whole brain death criteria and were supported in this by many renowned Muslim scholars. But there were many among the *ulema* who raised concerns that echoed those of Ramsey and Jonas.^v

The discussions in the Academy conference revolved around the issue of the soul and the definition of death. According to the teachings of the Quran and the *Sunna*, death is the moment when the *ruh* (soul) leaves the body. The question therefore was how to establish the time this severance actually occurred. The *fuqaha* in favor of the brain death criteria argued that as the Scriptures did not specify how to pinpoint this moment it was the responsibility of the “specialists” (physicians) to establish when death is determined to have occurred. Others argued in support that the human soul is “unmistakably linked to the brain,” and that the conclusion that brain death is the moment when the *ruh* leaves the human body can be arrived at by using the juristic principle of *ijtihad*.

Other *fuqaha* however believed, again using the Quran and *Sunna* as the primary basis of their argument, that in Islam humans are considered to be a combination of the body and the soul (unlike the Cartesian belief in duality of mind and body), and that there is no justification to emphasize one organ (the brain) as the locus for the soul rather than others such as the heart. Another objection offered was that Islam requires that death be ascertained with *yaqin* (certainty) and not merely through *zann* (legal probability). One scholar wondered poignantly how death could be said to have occurred with any *yaqin* following

brain death of a patient “if the body is still pulsating [with a beating heart] and life is full of mysteries.” Concerns were also expressed by some that the primary objective of instituting brain death criterion was to obtain organs. Others believed that acceptance of this criterion was akin to a step on the “slippery slope,” and that a day may come when an unconscious or insane person, one not meeting the *whole* brain death criterion, will be included in the category of the dead.^{vi}

So what is the status of whole brain death criterion four decades after it was first introduced? Despite academic discussions it continues to engender, it is now widely accepted, in addition to irreversible cardiopulmonary arrest, as a clinical, legally sanctioned means of pronouncing a patient dead. Having said this, readers will be interested, perhaps amazed, to learn that Pakistan remains the only country I am aware of that still, in 2005, lacks legislation to this effect. The relevant bill remains interred in the bowels of the Senate for the last ten years, waiting to be discussed. This has however not stopped physicians in Pakistan from using appropriate tests to establish brain death for many years when these are believed to be indicated.

In my opinion, neurological-based death criterion will continue to serve as a pragmatic, utilitarian approach to patients judged clinically to be in prolonged, irreversible coma, and whose cardiopulmonary functions are being maintained solely via invasive ventilatory support systems. And undoubtedly, this criterion will remain central to the success of the transplant enterprise; organs from brain death patients may offer in some cases the only way to save lives and bring hope of survival to many desperately ill patients.

Nevertheless, it is important for us to ponder on the reasons why to this day there remain stubborn pockets of resistance to brain death criterion both at religious and societal levels in so many countries. This is not by any means a phenomenon limited to the “uneducated” classes. In the United States, New Jersey State continues to allow orthodox Jews (and Conservative Christians) to claim “religious exemption” to the neurological criterion of death for self and family members. But perhaps the most wide spread resistance is reported from Japan which is considered to be among the most “modern,” industrialized countries of the world. It was only after a long debate on brain death and organ transplantation that in 1997, Japan finally managed to pass a law pertaining to these issues.

The Japanese law however includes a provision for families to choose between the cardiopulmonary and brain death criteria for declaration of death for themselves as well as for family members.^{vii} What is intriguing is that since this legislation has come into effect in Japan, organs from only 33 individuals declared brain dead have been used for transplantation in other patients.^{viii} This is considered by many to be a result of a shared Japanese ambivalence towards cadaveric donation unlike the case in other developed countries, and a deep societal discomfort at the concept of brain death and a perception of this as a mechanism, the *raison d’etre*, for retrieval of organs for transplantation into others.^{ix}

Whole brain death criterion is essentially a “re-definition” of the traditional human understanding of death. Legally and medically accepted although it has become over the years, nevertheless brain death remains a “clinical” death defined and engineered by the pragmatics of medical science. The concept is one which, notwithstanding all our medical “certainties,” still incites confusion and a sense of unease at a visceral level in many laypeople, and especially so when it is perceived as a medical modality for obtaining transplantable organs. Moreover, persistence of the use of the term “brain death” rather than “death” also points to a degree of ambiguity and conceptual unclarity about this concept among healthcare professionals themselves.^x These are important facets that cannot be excluded from our discussions if we wish to reach a better, more sensitive understanding of both, the diagnosis we call brain death and the stubborn resistance to it we continue to face.

References

- i Ivan Illich, *Limits to Medicine*, 5th ed. (London, UK: Marion Boyars Publishers Ltd, 1976): 207.
- ii Harvard Medical School, "A definition of irreversible coma. Report of the Ad Hoc Committee of the Harvard Medical School to examine the definition of brain death," *JAMA* 205:337-340, 1968.
- iii Paul Ramsey, *The patient as person* (New Haven: Yale University Press, 1970): 98-112.
- iv Hans Jonas, "Philosophical reflections on experimenting with human subjects," in *Experimentation with human subjects*, ed. P. A. Freund (New York: George Braziller Publishers, 1970): 26-28.
- v Ebrahim Moosa, "Languages of change in Islamic Law: Redefining Death in Modernity," in *Perspectives on Islamic Law, Justice and Society*, ed. R. S. Khare (Lanham, Maryland: Rowan and Littlefield Publishers, Inc., 1999): 161-197.
- vi This is not a base-less concern in view of the ongoing philosophical debate, particularly in the United States, about what constitutes a "person" who has legal and moral standing. This interesting debate is beyond the focus of this essay, but for those interested in discussions about "higher brain death" criterion I would recommend a recent article by one of the proponents of this idea. Robert M. Veatch, "The Death of Whole-Brain Death: The Plague of the Disaggregators, Somaticists, and Mentalists," *Journal of Medicine and Philosophy*, 30:353-378, 2005.
- vii M. Moroika, "Reconsidering Brain Death: A Lesson from Japan, Fifteen Years Experience," *Hastings Center Report* 31, no. 4: 41-46, 2001.
- viii Japan Organ Transplantation Network, <http://www.jotnw.or.jp/news/news.html>.
- ix Emiko Ohnuki-Tierney, "Brain Death and Organ Transplantation: Cultural Basis of Medical Technology," *Current Anthropology* 35, no. 3: 233-242, 1994.
- x Stuart J. Younger, C. Seth Landefeld et al, "Brain Death and Organ Retrieval: A Cross-sectional Survey of Knowledge and Concepts among Health Professionals," *JAMA* 261, no. 15: 413-418, 1989.

Useful Links

- Pakistan Organ Transplantation law: The transplantation of human organs and tissues: an ordinance. Ordinance Gazette of Pakistan, Government of Pakistan, 2007 (XLIII of 2007). <http://tx-society-pk.org/transplant%20law.pdf>.
- Syed Ali Anwar Naqvi, Bux Ali, Farida Mazhar, et al., "A socioeconomic survey of kidney vendors in Pakistan," *Transplant International*, vol. 20, no. 11 (2007): 934-939.
- James L. Bernat, "The boundaries of organ donation after circulatory death." *New England Journal of Medicine*, vol. 359, no. 7 (2008): 669-671.
- Anne Griffin, "Kidneys on demand," *BMJ* 15, vol. 334 (2007): 502-5.
- Sixty-Third World Health Assembly, "WHO guiding principles on human cell, tissue and organ transplantation," (2010): 413-419.
- Farhat Moazam, Aamir M. Jafarey, Bushra Shirazi, "To Donate a Kidney: Public perspectives from Pakistan," *Bioethics*, vol. 28, no. 2 (2012): 76-83.

Ethics of Physician-Pharmaceutical Industry Interactions

6.1: Conflict of interest
6.2: Practical issues and Guidelines

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Case for Discussion

Rota virus infection is a major cause of infant mortality in developing countries. Prevention has been shown to be effective with a vaccine called “Cure” which also significantly reduces mortality from the illness. Because of its effectiveness, the government recommends all infants be vaccinated with it. Company X in Pakistan manufactures the vaccine and makes it available to medical stores that sell it to patients at a set market retail price.

Dr. Dar, a renowned pediatrician is approached by the representative of Company X. He offers to provide the “Cure” vaccine to Dr. Dar for his clinic at a subsidized rate which is 30% less than the set market retail price, but Dr. Dar can sell the vaccine to patients at the retail price. Company X will also provide a refrigerator for storing the vaccine and a UPS system ensuring continuous refrigeration during power failures. The sales representative tells Dr. Dar that he could provide a “one stop” service to patients and families so they would not have to go to the medical store to buy the vaccine and the child would be administered the vaccination by qualified personnel in Dr. Dar’s clinic. Looking at the patient turn out in the clinic, the representative says that Dr. Dar would have no problem in keeping the stocks rolling. Dr. Dar finds this offer appealing.

Are there any ethical issues in Dr. Dar accepting this offer?

How would you handle this kind of offer?

NBC Guidelines for Healthcare Professionals* Interaction with Pharmaceutical Trade and Industry**

1. Introduction

Healthcare professionals and pharma industry are an integral part of health care delivery system the world over. The prime beneficiary of the relationship of the two is the patient as long as this relationship is based on strong ethical principles. Ethical considerations in the recent years have been observed to be violated due to financial and economic interests. Thus this relationship has come under intense scrutiny and a lot of criticism during the last several years within Pakistan as well as globally.¹⁻⁴ Pharma industry and the companies making medical devices and products which help practicing modern medicine and healthcare professionals have to interact with the industry for developing new treatment, conduct studies besides implementing clinical trials.^{5,6} However, their impact on patient care, medical research, medical education, besides physicians professional relationship with the industry are concerns constantly being expressed by the general public as well as the medical press. At the same time one also hears voices which challenge these concerns and emphasize the positive value of these interactions which is also getting place in themedia.⁷⁻⁹

Physician's interaction with the pharmaceutical industry starts in the medical schools and continues till practice.⁹ The frequency with which healthcare professionals benefit from industry sponsored meals and samples decrease as they enter practice. However the frequency of receiving honoraria, conference travel and research funding increases as they become more busy in their practice.^{10,11} Studies have shown ,that receipt of money, gifts even of minor value can have an impact on physicians prescribing decisions.^{12,13} Concerns have been expressed that all this eventually increases the cost of medical treatment.¹⁴ It has also been pointed out that if the research is funded and sponsored by the companies, it has also been pointed out that if the research is funded and sponsored by the companies, it is more likely that the physicians conducting clinical trials will report favorable results.¹⁵ In view of these concerns, various countries have been addressing this issue, and there is a strong feeling that it is time to reassess the nature and extent of this relationship between healthcare professionals and the pharmaceutical trade and industry in Pakistan.

In order to address this issue many professional bodies both in the medical community and in the industry have established Codes of Ethical Practices which serve to guide, monitor and censure its members. These guidelines also extend to students and resident staff. Where these codes have been ineffectual Governments of some countries have introduced legislation with punitive penalties to curb unethical practices.

* Healthcare professionals (includes Physicians, Specialists, GPs / Family Physicians, Medical Students, Nurses).

** Trade and Industry (includes industry and trade engaged in the manufacturing and marketing of diagnostics, equipment/ machines, medical devices and pharmaceuticals).

* Finalized on June 1st, 2010.

Note: National Bioethics Committee in its meeting held at Islamabad on July 30th, 2009 had formed this sub-committee to draft these Guidelines. It was discussed in detail and finalized in NBC meeting held at Karachi on May 22nd, 2010.

2. General Principles

Physicians and health related professionals including those under training are expected to act in the best interest of the patient as failure to do so undermine the trust of public in healthcare professionals and its willingness to seek medical care. Several professional societies have developed their own guidelines to monitor the interaction of physicians with the pharmaceutical trade and industry. These guidelines also recommend that students and resident staff should also be informed as most of them are not aware of any such document or guidelines.¹⁶⁻²⁰ Recent efforts to develop such guidelines for Pakistan include the “Ethical Guidelines for Physician Pharmaceutical Industry interaction” formulated by Karachi Bioethics Group.²¹ Health related professionals should maintain professional autonomy and independence in the interest of the patients while avoiding any self-interest in prescribing and referral practices. Patient interest must be safeguarded. It should be a common and transparent practice to declare any involvement, specially the financial interests, through ties with pharma industry.

The following guidelines cannot anticipate every eventuality; hence there may be exceptions in unusual circumstances. But great care must be taken to ensure that while making any exceptions, the possible negative consequences must be kept in mind. All efforts must be made to ensure that well being of the patients and integrity of the medical profession is not compromised.

3. Medical Research

When healthcare professionals participate in research which may involve the financial interest of a company irrespective of the source of funding, any financial relationship with the companies raise serious concerns about the objectivity of the research findings². This relationship can include equity ownership in the company, receipt of royalty payments from the company, membership of the company advisory board, funding for participation in conferences and seminars, funding to professional associations and societies, consultation to the company besides participation in speaking engagements on behalf of the company. American Medical Colleges and the American Association of universities recommend that in case their own, spouse or children have financial interests, they should not participate in such research. The only exception can be initial clinical use of a device invented by a researcher which is unlikely to be pursued by other investigators and only when an acceptable plan for managing the conflict of interest created by such a relationship has been developed and implemented.

Recommendations

1. The study should only be conducted by an investigator after due disclosure and approval by the ERB/IRB of the Institution in line with the GCP guidelines and the rules and regulations of that Institution.
2. Every clinical trial must meet the current scientific and ethical requirements and the existing legal regulations and must conform to the internationally recognized principles of Good Clinical Practice.
3. It should be ensured that investigators responsible for or taking part in a trial may not put their credibility in question by taking part in marketing promotions for the product or procedure investigated.
4. Publication of negative findings is also important. As such it is critical that a mechanism be created within the study protocol to ensure publication of clinical significant findings including negative ones if any.
5. Drugs provided by the industry for research purposes should similarly be given to the relevant institutional committee (or pharmacy) designated for such work. Distinction must be made between drugs donated by a company to an institution as a philanthropic gesture and drugs provided for the purpose of research. Drugs intended for clinical trials must be labeled as such and differentiated from the commercial or physician sample packs.
6. Utilization of research funding should be at the institution’s discretion. The funding industry must not influence the research agenda, methodology employed, participant selection, data analysis or

publication of findings. All research proposals must be assessed and approved by the Institutions Ethical Review Committee (IERC) prior to initiation.

7. Research involving human subjects and/or human materials, whether healthcare funded or otherwise, should be approved by a properly constituted IERC/ REC of NBC which will be responsible for review of ethical issues including research agenda, informed consent, risks and benefits to participants, and communities etc.
8. In case the institution does not have its own IERC, ethical review must be sought from an Provincial Bioethics Committee or NBC for approval and of the funding by industry.
9. IERC should have multidisciplinary compositions. Besides clinicians ERC should have representation from non medical sectors.
10. Declaration of the funding by industry must be made by researchers in all publications and during presentations that emerge as a result of research.
11. The institution involved or individual researcher should also declare the nature and amount of funding received for research on its website and other appropriate forum.
12. Healthcare Professionals may accept an honorarium against the time of their involvement in a clinical trial/research study ensuring complete disclosure and without any conflict of interest, in the following cases:
 - a) Industry initiated trials / studies.
 - b) Investigator / Doctor initiated trials / studies.
13. The investigators who are involved in a trial should inform the academic institution for which they are working of the financial interests associated with their participation in any clinical trial/study.

3.1 Industry Sponsored Research: Funding from the pharmaceutical industry including those marketing medical devices should cover the actual costs of performing research including salaries of researchers and research staff, costs of various tests and investigations, procedures, medication, data analysis costs besides appropriate overheads. However, payments unrelated to actual cost and appropriate compensation for time utilized may influence the physician's decisions on enrollment of study subjects. Physicians should not participate in any such research study which involves payments not related to actual costs and appropriate compensation for the time spent. Concealment of unfavorable findings of clinical trials funded by companies threaten the integrity of medical research and the validity of data on which clinicians base their decisions. These acts may affect the patient care and researchers design for future investigations.^{22, 23}

Publication of negative findings is also important. As such it is critical that a mechanism be created within the study protocol to ensure publication of clinical significant findings including negative ones if any. Health related professions should refuse to participate as authors if they do not have full access to relevant data and ability to report results including adverse events.

The Association of British Pharmaceutical Industry (ABPI) in its guidelines on relationship with the medical profession recommends that physicians conducting clinical trials should expect realistic payment. All details regarding payment should be specified as part of the formal agreement including the purpose for which staff or equipment have been funded. Furthermore details relating to such clinical trials must be submitted to the local Research Ethics Committee or the institution along with the trial protocol. Meetings organized for groups of healthcare professionals, health officials, administrative staff of hospitals which are wholly or mainly of social nature should not be sponsored by the industry.

Before being enrolled in any research the study subjects have the right to know if the researchers have any financial relationship with the pharmaceutical company sponsoring the study. Hence it is mandatory that the study subjects are told in clear terms about such a relationship before asking for their consent to participate in the study. In all such cases the researchers are expected to comply with the necessary applicable disclosure requirements of their respective institutions or funding agencies.²⁴

3.2 Industry Sponsored Surveillance Studies: These studies must not be market oriented; instead these should be meant for advancement of science related to a recently marketed drug in which the drug is used in a large number of patients in a real life situation. Observations about the efficacy of the drug are desirable but more importantly the primary objective is to document the adverse event profile, especially the uncommon ones which may not show up in relatively smaller number of patients studies in the phase 2 and 3 clinical trials. These studies should also go through appropriate Ethics Review Committee approval.

3.3 Authorship of Research Findings: Sometimes it is the employees of the pharmaceutical companies who draft and revise these research reports and findings and their role is not mentioned in the acknowledgements. It makes it extremely difficult for the Editors, reviewers as well as readers to ascertain the reliability and validity of the data and their interpretations which are being presented. Ghost writing also involves listing authors who have not played any meaningful, intellectual role in writing or revising the paper but their names do appear on the paper as authors. It is recommended that all authors must be acknowledged and their role in research as well as preparation of the manuscript must be accurately described. They should strictly abide by the authorship criteria laid down by the International Committee of Medical Journal Editors (ICMJE).²⁶ The authorship credit should be based on substantial contributions to conception and design, acquisition of data or analysis and interpretation of data, drafting the article or revising it critically for important intellectual content and final approval of the version to be published. Financial support for the preparation of the manuscript, if any, should also be disclosed.

4. Continuing Medical Education and Professional Development

Most medical institutions in Pakistan have no faculty development programme. As a result, healthcare related professionals and faculty rely on the pharmaceutical industry's assistance to attend international conferences, seminars and workshops within and outside the country. It is not possible for many to even participate in such academic activities within the country in the present circumstances. Hence, Pharma industry support for such CME and CPD programs is inevitable but it must be ensured that such facilities are not misused and abused. Studies have shown that accepting funding to attend such academic activities is often associated with increased requests for addition of their drugs in the hospital's formulary.²⁷ It also influences the physicians prescribing practices.

4.1 Traveling and Lodging to Attend Academic Activities: It is unethical for industry sponsored healthcare professionals who are attending academic activities within country or abroad to simultaneously request for the sponsorship of their spouses/children or family members. The sponsorship should not include pleasure trips and sightseeing. All pharmaceutical companies and those involved in marketing medical devices must furnish details of the healthcare professionals sponsored by them for visits within the country and abroad every month to the National Bioethics Committee secretariat and the Ministry of Health. This information will be posted on the NBC website as public information. Regular reporting and accessibility to such activities will discourage unethical practices.

4.2 Sponsored CME Programs: Pharmaceutical sponsored CME programs affect presentation contents wherein the sponsor's drug is always preferentially highlighted. Some of the speakers even repeatedly use their brand names while comparing it with other generic drugs. This practice results in undue favor of sponsor's drug.²⁸

4.3 Pharma Company Employed Speakers: Often Pharma industry employs medical graduates or medical advisors who act as speakers at company sponsored meetings, thus promoting their own drugs under the disguise of scientific meetings/CME programs.²⁹ This results in biased treatment decisions by the health professionals. It is generally agreed that Pharma industry employed speakers should be banned to give lectures in conferences/CME.^{30,31}

4.4 Satellite Symposia: Pharma industry sponsored satellite symposia organized at breakfast, lunch or dinner time during conferences should be discouraged.

4.5 Medical Conferences: In Pakistan billions of rupees are spent each year by the pharmaceutical industry on hosting medical conferences in hotels. The industry passes on this burden to the patients in the form of high cost of medicines/devices. In order to reduce the cost of the medicines it is imperative that the medical conferences must return to the lecture halls and auditoriums except in exceptional situations where such facilities are not available. With the passage of time these facilities should be created in all institutions.

Attempts should be made by the Healthcare professionals to generate resources from within their institutions and from personal contributions. Since continuing medical education (CME) or scientific and educational conferences or professional meetings can contribute to the improvement of patient care, therefore, financial support from healthcare companies in its organization of such meetings / CME is permissible. Cash transactions or direct payment to the conference organizers from the Pharma trade and industry should be discouraged. Direct payment may be made to the catering firms, audiovisual service providers etc. Financial support and donations should always be in the form of certified cheque/draft deposited in the institutional/association/organization accounts. Funds generated must be declared on website and /or published and is able to withstand public and professional scrutiny.

1. The primary purpose of an educational meeting must be the enhancement of medical knowledge and the quality use of medicines. Physician's involvement in these events must have the objective of gaining current, accurate and balanced medical education in an ethical and professional manner. When a Congress / Symposia are organized, a **minimum of 70 per cent of time** should be spent on core agenda activities of the Congress/Symposia and a **maximum of 20 per cent of time** may be devoted to recreational personal activities, secondary to the main purpose.
2. Healthcare professionals should not demand or accept invitations to the pleasure trips & outings (not associated with academic activities) or the hospitality from the industry in the form of passes or tickets to attend expensive games or music concerts etc. just for the sake of entertainment.
3. There should be a modest working lunch in the conferences. Conference participant name badges should not contain any company or product logo. No product, company banner should be displayed inside the meeting hall nor should any lucky draws be permitted during the meeting. Back drop at the conference venue should not contain the name of any company or product. All these activities should be restricted to the Exhibition area.
4. Continuous Professional Development committee of PMDC or some other agency should issue CME credit for all such academic activities based on their scientific programme. Such a system will encourage organizers to strengthen & improve the scientific contents of these meetings.
5. All the speakers must declare their financial relationships/ sponsorship if any with the industry in their presentations. Pure drug promotional presentations should not be allowed as a part of the main scientific programme.
6. Air travel for healthcare professionals attending a company educational meeting, if needed to be provided by the industry partner, must be by economy class only. Physician may accept hospitality of a trip/journey from companies to another city within country or to a foreign country if there is an academic component/activity during the trip, if he/she is presenting a scientific paper/lecture or participating in a scientific board or meeting.
7. Healthcare professionals should not accept or demand hospitality of a trip/journey for their spouse/children/family members from industry within country or abroad.
8. Healthcare professionals should not accept invitations/coupons to company sponsored meals, Iftar dinners or any other invitations which are not associated with any academic activity.
9. Funding should not be accepted by the Healthcare professionals to compensate for the time spent attending the conference or meeting.

10. Healthcare professionals should not receive any cash or monetary grants from any pharmaceutical and allied healthcare industry for individual purpose, which is not related to any academic activity or patient benefit.
11. Healthcare Industry and the medical societies should declare any sponsorship, grants, financial support etc. provided to any Health Care Physician/Institution on their website and also on NBC website, or if required declared to the Regulatory Authorities. However, no grants should be provided to organizations that do not provide detailed financial account of their conferences to its members or display it on their websites.

5. Drug Samples

Pharmaceutical industry distributes free drug samples to physicians worth billions of dollars all over the world each year.³² The quantity of these samples in Pakistan is 2-3% of pharma market which is worth twenty to thirty million rupees. The purpose of these samples is to familiarize doctors about a drug but studies have shown that distribution of these samples significantly influences the decisions of the physicians and hence are considered useful and effective marketing technique.³³⁻³⁵ Distribution of these free samples encourages physicians to start patients on these more expensive medications. In some cases physicians feel obliged and become dependent on the medical representatives for continued free supply of these drug samples for their patients. Some healthcare facilities abroad and within Pakistan have established mechanisms where these free samples are deposited at a central place for distribution to deserving patients.

Recommendations

Physicians must limit the use of free drug samples in the best interest of patient care. All healthcare facilities should work out a system of central collection of samples e.g., hospital pharmacy for further distribution to deserving patients.

6. Medical Representatives Visit to Healthcare Facilities:

Medical representatives visit healthcare facilities during the morning/peak working hours which affect the teaching, training and patient care. Many healthcare facilities have now limited the activities of these representatives and prohibit their visit to patient care areas.¹³

Recommendations

Healthcare facilities should fix some timing on particular days of a week for the visit of these medical representatives and this must be implemented in letter and spirit. However healthcare professionals should not rely on these representatives from the industry as their primary source for drugs and treatment related information.

6.1 Gifts, Giveaways, Vacations and Support for Clinic Refurbishing: The practice of expensive gifts, giveaways, financial support for vacations in and outside the country and setting up the clinics and even support for children's weddings has been observed. This is highly unethical and induces the physician to prescribe a product or group of products of a specific pharma company.

In dealing with healthcare industry, a healthcare professional shall always ensure that there shall never be any compromise either with his / her own professional autonomy and / or with the autonomy and freedom of the medical institution / association. To avoid conflict of interest, gifts, items or benefits are to be discouraged and should not be accepted by the healthcare professionals, keeping in view the larger interest of the profession and to remain very careful. Nothing should be accepted or demanded by the healthcare professional in a manner or on conditions that would interfere with the independence of their professional prescribing practice.

1. Healthcare professionals should not accept a gift, benefit in kind or economic advantage as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine / product.
2. Healthcare professionals may accept promotional aid items from the healthcare industry that primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered (such as stethoscope, BP apparatus, weight machine, tongue depressor, hand wash etc.). Personal Items (e.g. Mobile Phone, Laptop, Car, AC etc.) and cash payments are specifically not acceptable.
3. Healthcare professionals may accept text or reference-books/information; medical journals, CDs and other educational material if they serve a genuine educational function and should be subscribed in the name of Hospital / Institute.
4. Healthcare professionals should not enter into a written or verbal deal / agreement of any kind with healthcare industry against any service or support from them for personal gains or for the benefit to the Hospital/Institute (donations in cash or kind) or for the patient against providing support for generating prescriptions.
5. Promotional items of insignificant value, provided free of charge, are permissible as long as they are related to the Healthcare professional's work and/or entail a benefit to patients.

Health care professional are responsible for and must ensure that any discount received from the suppliers is passed on to the patients and practitioners do not use it as an inducement to generate financial rewards

7. Role of Professional Specialty Organizations

Professional specialty organizations are playing a vital role in keeping the healthcare professionals abreast of latest developments in medicine through publication in journals, annual conferences, hands on workshops, seminars and symposia. Most of these activities are funded or sponsored by the pharmaceutical trade and industry. This can influence clinical decision making and undermine the reputation of the medical profession, and the integrity and credibility of the professional specialty organizations. It is important that the organizers or office bearers of these organizations distinguish education from marketing activities. They have a duty to provide their members the best scientific evidence as regards efficacy and suitability of drugs and equipment, instruments used in clinical practice. Great care must be taken to separate it from the industry's promotional activities.

Recommendations

These organizations must prepare a scientific program and select speakers and their topic independent of the pharma sponsored speakers. Industry funding should not influence the scientific programme. Relevant committees of the organizations should provide a transparent account of all expenditures following all sponsored activities to its members.

8. Product Endorsement

It is unethical for professional specialty organizations to endorse commercial products. In Pakistan certain organizations and individuals have provided their seal of endorsement on tooth pastes, certain foods and soaps, health insurance, nutritional products etc, in the print and electronic media. With or without donation or payment healthcare professionals must not allow their name or logo to be attached to a commercial product or service in order to safeguard professional integrity. (Some other specific guidelines are covered in the section on Medical Conferences).

8.1 Peer-selling: Physicians should not be involved in the unethical practice of peer- selling the product. This involves an expert on the subject giving talks (and endorsement of the product) to a small group of doctors focusing on a product or a device. Generally a series of such meetings are held throughout the country, especially for the newly introduced products designed to increase the sale of such products.

8.2 Affiliations: The healthcare professionals and senior management and CEOs of institutions providing healthcare to patients, serving on the Board of pharmaceutical industry is a source of major conflict of interest. Healthcare professional may work for pharmaceutical and allied healthcare industries in advisory capacities, as consultants, researchers, speakers, treating doctors or in any other professional capacity. In doing so, a healthcare professional shall ensure, that his professional integrity and freedom are maintained, patient's interest is not compromised, affiliations are within the law and such affiliations / employments are fully transparent and disclosure is made explicitly in an agreement.

9. Creating a Balance

The healthcare professionals and pharma industry are integral part of health delivery system. It is important to balance conflict of interest against overly restrictive policies. In this situation prohibition of pharma industry funding for CME/CPD or availability of drug samples for needy patients, could have negative consequences in patient care. These guidelines are being prepared to create awareness of the unethical practices amongst the stake holders, ensure oversight agencies to monitor mal practices and take punitive actions against defaulters. Create forums where ethics committees of professional medical bodies, pharma association's representatives from MoH and NBC can meet and decide about penalty on defaulting members and their unethical activities.

Voluntary observation of ethics guidelines is the best way for all concerned to avoid potential legislative action by the authorities. These guidelines are intended to be a living document which can be amended from time to time, or updated when new issues are highlighted which require attention.

10. Acknowledgement

For the preparation of these guidelines the authors have benefited from the following documents that is gratefully acknowledged:

1. Association of British Pharmaceutical Industry (ABPI) guidelines on relationship between the medical profession and the pharmaceutical industry.
2. Professional Medical Associations and their relationship with Industry. A proposal for controlling Conflict of Interest. JAMA June 21st 2009.
3. Report by American Psychiatric Association Working Group on Relationship between psychiatrists and the pharmaceutical and Medical Device industry.
4. Physicians and the Pharma Industry: Is a Gift Ever Just A Gift? JAMA June 21st 2009.
5. Pakistan Hypertension League: Guidelines for scientific meetings and annual conferences concerning scientific, ethical and organizational issues. Revised in March 2009.
6. Guidelines for physicians in Interaction with industry.2007; Canadian Medical Association.

References

1. Brennan TA, Rothman DJ, Blank L, et al.: Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. JAMA 2006; 295:429-433.
2. Bekelman JE, Li Y, Gross CP: Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA 2003; 289:454-465.
3. Jawaid SA, Jafary MH. Relationship between the medical profession and the pharma industry. Need for greater scrutiny, transparency and accountability. Pak J Med Sci 2004; 20(4): 283-291.
4. Jawaid SA. Annual Heart Mela at PC Burbhan. (Off the Record) Pulse International (September 15th) 2009; 10(18)1-7.
5. Johns MME, Barnes M, Florencio PS: Restoring balance to industry-academia relationships in an era of institutional financial conflicts of interest: promoting research while maintaining trust. JAMA 2003; 289:741-746.
6. Thase ME: On the propriety of collaborations between academicians and the pharmaceutical industry: An alternate viewpoint. World Psychiatry 2007; 6:29-3.
7. Stossel TP: Has the hunt for conflicts of interest gone too far? Yes. Brit Med J 2008; 336:476.

8. Stossel TP: Regulation of financial conflicts of interest in medical practice and medical research. *Perspectives in Biology and Medicine* 2007; 50:54–71.
9. Hoges B. Interaction with pharmaceutical industry. *CMAJ* 1995; 153:553-559.
10. Lurie N, Rich EC, Simpsor DE. Pharmaceutical representatives in academic medical centers. *J Gen Intern Med* 1990; 5:240-243.
11. Strange D, Gangron M, Molloy W. National survey of the attitude of Canadian Physicians towards drug detailing by pharmaceutical representatives. *Ann R Coll Physicians Surg Can.* 1996; 29:474-478.
12. Perlis R, Perlis C, Wu Y, Hwang C, Joseph M, Nierenberg A: Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry. *Am J Psychiatry* 2005; 162:1957-60
13. Wazana A: Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA* 2000; 283:373-380.
14. King-Casas B, Tomlin, Anen C, Camerer CF, Quartz SR, Montague PR: Getting to know you: reputation and trust in a two-person economic exchange. *Science* 2005; 308 (5718): 36.
15. Donohue JM, et al. A decade of direct-to-consumer advertising of prescription drugs. *N Engl J Med* 2007; 357:673-681
16. Canadian Medical Association. Physicians and the pharmaceutical industry (update1994). *CMAJ* 1994; 150:256A-256F.
17. Royal College of Physicians and Surgeons of Canada. Guidelines for support o continuing medical education by industry. Available at: http://rcpscstest.medical.org/english/public/policy/cme_e.html. Accessed December 8 1999.
18. Council on Ethical and Judicial Affairs, American Medical Association. Gifts to physicians from industry. *JAMA*.1991; 265:501.
19. Guidelines for faculty involvement in commercially supported continuing medical education. *Acad Med* 1992; 67:615-621.
20. American College of Physicians. Physicians and the pharmaceutical industry. *Ann Intern Med*.1990; 112:624-626.
21. KBG Guidelines are available at [http://karachibioethicsgroup.org/PDFs/ Karachi Bioethics Group Ethical Guidelines. Pdf](http://karachibioethicsgroup.org/PDFs/Karachi%20Bioethics%20Group%20Ethical%20Guidelines.Pdf)
22. Turner EH, Matthews AM, Linardatos E, et al.: Selective publication of antidepressant trials and its influence on apparent efficacy. *N Engl J Med* 2008; 358:252-260.
23. Psaty BM, Kronmal RA: Reporting mortality findings in trials of rofecoxib for Alzheimers disease or cognitive impairment: a case study based on documents from rofecoxib litigation. *JAMA* 2008; 299(15):1813-7.
24. Weinfurt KP, Dinan MA, Allsbrook JS, Friedman JY, Hall MA, Schulman KA, Sugarman J: Policies of academic medical centers for disclosing financial conflicts of interest to potential research participants. *Acad Med* 2006; 81:113-8.
25. Ross JS, Egilman DS, Krumholz HM: Guest authorship and ghostwriting in publications related to rofecoxib: a case study of industry documents from rofecoxib litigation. *JAMA* 2008; 299:1800-1812.
26. International Committee of Medical Journal Editors: Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (updated October 2008), accessed at www.icmje.org.
27. Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. *JAMA* 1994; 271:684-689.
28. Bowman MA, Pearle DL. Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *J Contin Educ Health Prof* 1988; 8:13-20.
29. Ziegler MG, Lew P, Singer BC. The accuracy of drug information from pharmaceutical sales representatives. *JAMA* 1995; 273:1296-1298.
30. Caudill TS, Johnson MS, Rich EC, McKinney WP. Physicians, pharmaceutical sales representatives and the cost of prescribing. *Arch Fam Med* 1996; 5:201-206.
31. McKinney WP, Schiedermayer DL, Lurie N, Simpson DE, Goodman JL, Rich EC. Attitudes of internal medicine faculty and residents toward professional interaction with pharmaceutical sales representatives. *JAMA* 1990; 264:1693-1697.
32. Cutona SL, Woolhandler S, Lasser KE, et al.: Characteristics of recipients of free prescription drug samples: a nationally representative analysis. *Am J Pub Health* 2008; 284-289.
33. Pey MY, Peay ER: The role of commercial sources in the adoption of a new drug. *Soc Sci Med* 1988; 26:1183-1189.
34. Adir RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. *Am J Med* 2005; 118(8): 881-4.
35. Boltri JM, Gordon ER, Vogel RL. Effect of antihypertensive samples on physician prescribing patterns. *Fam Med* 2002; 34 (10): 729-31.

Definitions

Health Care Provider may refer to a health professional or an organization that provides services of a health professional

Health Care Professional includes members of the medical, dental, Healthcare and nursing professions, Pharmacists and any other persons, who in the course of their professional activities and delivery of patient care may prescribe, recommend, purchase supply (or influence the supply) or administer a medicine

Physician is Doctors with basic Medical/ dental qualification or basic Medical/ dental qualification with post graduate degree/ diploma or with equivalent qualification in any medical discipline registered with PMDC

Health Care Industry The Global Industry Classification Standard and the Industry Classification Benchmark divide the industry into two main groups:

1. **Health care equipment & services** comprise companies that provide medical equipment, medical supplies, and health care, such as hospitals, home health care providers, and nursing homes, ambulatory care specialist and general medical practitioners (GP's)
2. **Healthcares, biotechnology & related life sciences** comprise sectors companies that produce biotechnology, healthcares, and miscellaneous scientific services.

Substantial Value of Gift / Promotional Aid Item: Any gift / item bearing worth of PakRs.2000 only.

Medicine means any branded or unbranded medicine intended for use in humans which requires a marketing authorization as defined in Drug Act 1976

Representative means a representative of health care industry calling on members of the health professions and administrative staff in relation to the promotion of medicines.

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http://karachibioethicsgroup.org/PDFs/Karachi_Bioethics_Group_Ethical_Guidelines.pdf

Karachi Bioethics Group Institutional Ethical Guidelines for Physician Pharmaceutical Industry Interaction

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Preamble

The pharmaceutical-physician relationship is drawing increasing attention all over the world in recent years due to the conflicts of interest inherent in interactions of physicians with the industry. There is a real, well demonstrated potential for physicians to lose their impartiality in prescribing drugs under the influence of their relationship with the industry.^{1,2,3,4,5,6} It is imperative that we guard against any and all threats against the objectivity of the medical decision making process and endeavor to maintain the professionalism and nobility expected from members of the medical profession. It must not be forgotten that the medical profession is regarded above all other professions as 'a moral enterprise, based on a covenant of trust.'⁷

Unfortunately, the ethical core value of medical practice is being seriously threatened due to the rampant commercialization that is rapidly turning medicine into a business enterprise. This has particular significance for developing countries like Pakistan where the absence of legal, ethical and moral frameworks, weak regulatory mechanisms and an expanding pay-for-service health system offers greater opportunities for exploitation of patients who are often illiterate and unaware of their rights.

The relationship between the pharmaceutical industry and the medical profession is coming under much scrutiny globally. There is growing disquiet among medical professionals and the public is demanding greater transparency in the interactions. In many countries there is a move to redefine this relationship, through legislation and drawing up of new codes and guidelines. The Sunshine Act, 2008 in the USA is one such example.⁸

The Act provides for "transparency in the relationship between physicians and manufacturers of drugs, devices, biological, or medical supplies" and mandates reporting to the government "transfer of value to a physician" by the manufacturers.

The need for such an ethical framework in Pakistan has also been voiced for several years by concerned members of the medical community as well as by the general public. As things stand, there is little or no regulation of medical practice in Pakistan and physicians are at liberty to interact as they please with the industry.

Stories abound about the gifts being handed down to physicians by the industry, starting from insignificant trinkets such as pens and coffee cups, to favors such as air tickets for physicians and their families to resorts ostensibly for CME events, payment of monthly dues for leased cars and even refurbishing of private residences.^{9,10} What is alarming is that there appears to be no serious effort to curb such practices in Pakistan, and physicians have come to expect such perks as their right. This is in marked contrast to efforts being taken to stem these practices in the developed world.

We believe that if medical professionals in Pakistan are to regain public trust and reestablish their credibility, then it is essential that their actions are grounded in ethics and morality, and their conduct is guided by a sense of personal integrity and professionalism. Moving towards ethical pharmaceutical-physician relationships constitutes a significant aspect of achieving this goal.

It is against this prevailing background in Pakistan that development of the PPI guidelines was undertaken by the KBG. The aim is to provide an ethical framework to guide the physician-pharmaceutical industry interactions in Pakistan in order to move from what is to what *ought to be*.

Process of Development of the Guidelines

The Karachi Bioethics Group (KBG) comprises individuals from different institutions in Karachi who share an interest in bioethics. The KBG was established in 2004 and since then is meeting every other month in one of the members' institutions each year, chosen on a rotational basis. (For a list of members and their institutions see Appendix 1.) In 2008, the KBG took upon itself the project of developing a set of guidelines for physician-pharmaceutical industry interactions. This was stimulated by rising concerns among physicians as well as the lay public about reports of unethical practices and increasing influence of drug and device companies on physicians.

Consequently, a working group was developed within the KBG which met on several occasions to develop these guidelines. The working group went through several sets of guidelines already available (see Appendix 2), and took opinions from several physicians within and outside Karachi working at various institutions. Drafts were presented to the KBG over two meetings in which intense discussions took place before finalizing the guidelines. There was a variety of opinions within the group with some considering the guidelines as too idealistic to work within our environment. Some KBG members pointed out however that similar practices were already in place in their institutions and therefore are realistic and possible.

The document that follows represents the consensus of KBG members and was reviewed in 2011. These guidelines primarily focus on physicians working in institutions and can serve as a resource for development of institutional guidelines.

Broad Principles

It should be the responsibility of health care organizations and academic institutions to cater to the educational, training and research requirements of their students, trainees, staff and faculty. One to one interactions between individual physician and pharmaceutical industry representatives for any purpose should be strongly discouraged to minimize the possibility of influence in the prescribing practices of the physicians. Any interaction between the medical fraternity and the industry required for the transfer of information regarding new products and innovations must be channeled through designated institutional processes.

These guidelines suggest the creation of a transparent process for conducting such activities for fund generation.

It is recommended that a common pool of money meant for CME and similar activities be created by the institutions and that funds from different sources including pharmaceuticals be kept in this pool. Institutions should develop transparent mechanisms to maintain and utilize funds from this common pool (see Appendix 3 for elaboration).

Disclosure

Definition: Disclosure is defined as the act of revealing (publicly) or uncovering.

Health care institutions should declare/disclose:

- Details of any support (cash or material) obtained by them from the pharmaceutical industry

Health care workers should declare:

- Details of their personal or their immediate families' financial involvements that may create a conflict of interest (see appendix 4 for definitions). These can include directorships/partnerships/

- shares in any pharmaceutical industry/medical supplies producer/retailer
- This also includes ownership/partnership in hospital/clinic/pharmacy/chemist shop/optician shop/laboratory/radiology unit or any other similar business

Suggested mechanisms for disclosure:

- Institutional Website
- Disclosure register accessible to physicians and staff

Gifts/Giveaways/Drug Samples

Accepting gifts of any kind and value from the pharmaceutical and device industry leading towards personal gain has the potential of influencing the physicians prescribing practices. This raises a situation of conflict of interest and should be avoided. We recommend that:

- One-to-one contact between physicians and the pharmaceutical industry representatives should be strongly discouraged
- Physicians should not accept gifts of any kind and value from the pharmaceutical industry
- The pharmaceutical industry should deposit all drug samples and giveaways with a designated institutional committee and not individual physicians. These can be then used to cater to the needs of poor patients
- All medicines, equipment, books, travel support or any other money or material should be collected in a special pool overseen by a designated institutional committee. Members of the committee should command respect of all stakeholders as ethical individuals. Donors should have no influence over the utilization of funds from this common pool
- Institutions must develop transparent mechanisms for disbursement of such funds making these known to all stakeholders
- It is preferable that items such as books or equipment etc. donated by the industry should not display the name of a drug or product. The company logo and name can be displayed inconspicuously

Scholarships and Educational Grants

Educational and other academic grants and support should ideally be provided by academic institutions. However, given the paucity of funds in academic institutions, reliance on pharmaceutical support cannot be entirely excluded. Scholarships, special grants and educational funds from pharmaceutical companies obtained by institutions for the trainees and faculty members should use the following guidelines:

- All funding should be directed to the institution and not individuals. It should be placed in a common pool established specifically for such donations/grants from the industry and meant for education. This common pool should be managed by a committee designated with the responsibility of handling such money
- It should be for the institution, based on its policy for CME/educational activities, to decide how the money from this common pool is to be utilized without influence of the donor

pharmaceutical companies

- Recipients of grants should declare the utilization of such funds on the institutional website or in a publicly accessible register kept for such records
- The physician working in an institution should not enter into contractual agreements with pharmaceutical companies
- If a physician is invited by a pharmaceutical company to present his/her own research data regarding one of their products, the physician may do so provided the following conditions are met:
 - The pharmaceutical industry has first approached the institution through its established process
 - If funding for attending the event is involved, it is made available to the physician through the institution
 - The physician should declare/disclose pharmaceutical industry support prior to his/her presentation

Research

Ideally, all research funding should be provided by institutions. However, currently, support by pharmaceutical funding for research is a global reality. Research support from pharmaceutical industry should occur using the following guidelines:

- There should be no direct payments to the researcher / investigator by the industry for conducting research studies. All such research funding should be made to an appropriate institutional committee established for this function
- Drugs, equipment or other consumable provided by the industry for research purposes should similarly be given to the relevant institutional committee designated for such work. Distinction must be made between drugs, equipment or consumable donated by a company to an institution as a philanthropic gesture and drugs provided for the purpose of research
- Utilization of research funding should be at the institution's discretion. The funding industry must not influence the research agenda, methodology employed, participant selection, data analysis or publication of findings. All research proposals must be assessed and approved by the Ethical Review Committee (ERC) prior to initiation
- Research involving human subjects and/or human materials, whether pharmaceutical funded or otherwise, should be approved by a properly constituted ERC which will be responsible for review of ethical issues including research agenda, informed consent, risks and benefits to participants and communities, etc.
- In case the institution does not have its own ERC, ethical review must be sought from an external ERC
- Declaration of the funding by industry must be made by researchers in all publications and during presentations that emerge as a result of research
- The institution involved should also declare the nature and amount of funding received for research on its website and other appropriate fora

Pharmaceutical Industry Funding for CME Events

Large CME events including conferences, seminars, workshops etc should ideally be funded by academic institutions utilizing their own funds. Institutions can begin by relying on their own resources to hold events like guest lectures on a modest scale. Given the paucity of resources available to health care and academic institutions, they may have to turn towards the industry for support for larger events.

Pharmaceutical company organized drug information talks when arranged for updates should be held in hospitals and institutions and not in hotels, and should not include meals.

If industry support is required for organizing large educational events, it should be kept in mind that:

- All such support should come to the institution from a common pool created and maintained for this purpose and should not be directed towards individuals
- Utilization of such funds should be at the discretion of an institutional committee responsible for organizing the event, without any influence of the funding agency
- Pharmaceutical funding should not be sought for recreational or social events like a trip to the beach or a family day at an amusement park, etc.
- If a CME has a social event like a gala dinner or a musical evening, the event should not be held with donated funds and should be financed through sale of tickets to the audience
- All industry support should be declared on the institutional website or using any other appropriate means
- Any advertising done by the funding industry at the time of a CME event needs to be done in a dignified and professional manner. There should be no advertising banners, hoardings, posters or any other material allowed within the academic/conference area. There should be a separate place designated for advertising activities so that the integrity of the academic arena is preserved
- A declaration should be made by the pharmaceutical companies detailing their support for the CME event on their company website
- The practice of flying in 'foreign experts' by the pharmaceutical companies should be discouraged. Since they are on a paid/supported tour, these experts can hardly be expected to present a non-biased, purely academic opinion in their talk due to the conflict of interest. Physicians should be encouraged to avoid such sponsored seminars and instead seek such drug information from relatively independent sources such as Cochrane Collaboration and other similar resources available on the internet

Promotion of Products

Noting the unique status that physicians enjoy in society, it is recommended that they should not participate in product promotional activities like making appearances in advertisements, TV talk shows etc., meant to promote a product or brand. Institutions should consider developing a policy for their health care workers to check such occurrences.

If physicians are participating in public awareness programs on the media, the individual and institution should ensure that their appearance is governed by ethical principles and does not involve any financial or other personal gain introducing the element of conflict of interest. The primary focus of such non-promotional activities should only be the improvement in the health of the society.

Appendix

Appendix 1 List of KBG members (At the time of developing the Guidelines)

1. Aamir Jafarey	Centre of Biomedical Ethics and Culture, SIUT
2. Aasim Ahmad	The Kidney Centre
3. Arshi Farooqui	Aga Khan University Hospital
4. Bushra Shirazi	Ziauddin University Hospital
5. Farhat Moazam	Centre of Biomedical Ethics and Culture, SIUT
6. Kausar S Khan	Aga Khan University Hospital
7. Khawar Mehdi	Pharm Evo
8. Maqbool Jafary	Karachi Institute of Heart Diseases
9. Mazhar Nizam	Patel Hospital
10. Moin Siddiqui	Ziauddin University Hospital
11. Mumtaz Lakhani	Ziauddin University Hospital
12. Murad Khan	Aga Khan University Hospital
13. Naila Rahman	Patel Hospital
14. Naima Zameer	National Institute of Child Health
15. Nausheen Saeed	Ziauddin University Hospital
16. Nida Wahid Bashir	Patel Hospital
17. Rehana Kamal	Aga Khan University Hospital
18. Riffat Moazam Zaman	Aga Khan University Hospital
19. Rubina Naqvi	Sindh Institute of Urology and Transplantation
20. Salahuddin	Hamdard University Hospital
21. Samrina Hashmi	Pakistan Medical Association
22. Shahid Shamim	Dow University of Health Sciences
23. Shaukat Ali Jawaid	Pulse International
24. Shifa Naeem	Freelance Practitioner
25. Tayyaba Batool	National Institute of Child Health
26. Tufail Bawa	Patel Hospital
27. Yasmin Wajahat	Sobhraj Maternity Hospital

Appendix 2

Documents Consulted

The WG-PPT would like to acknowledge the following documents/guidelines which were consulted in the process of compilation of the present guidelines.

- Code of Medical Ethics of the Pakistan Medical Association
- Guidelines for physicians in interactions with Industry. Canadian Medical Association Policy 2007.
- Guidelines for ethical relationship between physicians and industry. The Royal Australian College of Physicians. Third edition 2006
- Royal College issues new guidelines on gifts from drugs companies Ann McGuaran. London (<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1124049>)
- The relationship between physicians and the biomedical industries: advice of the Royal College of Physicians (http://www.rcplondon.ac.uk/news/statements/advice_biomedindustry.htm)

Appendix 3

Regulating Committee

Since KBG guidelines emphasize limiting interaction of health care workers with industry except through institutional routes, it is imperative that institutions devise transparent and acceptable mechanisms to do so. One such way is for institutions to constitute specifically mandated committees consisting of representation from all stakeholders including physicians, pharmacists and hospital administration in acceptable proportions. Institutions may even consider inclusion of lay members from outside the institution to enhance credibility.

In order for it to be viable, this committee should command the respect of all segments of the institution. It is this committee that should interact with the industry and be responsible for allocation of funds for CME or other relevant activities within the institution. Institutions should develop clear terms of reference for the working of this committee.

It is also recommended that institutions undertake educational efforts to enhance bioethical awareness among its staff and faculty.

Appendix 4

Definitions

Conflict of Interest: A situation that has the potential to undermine the impartiality of a person because of the possibility of a clash between the person's self-interest and professional or public interest.

Conflict of Interest in Medicine: Conflict of interest exists in medicine when the physician's primary responsibility to the patient is influenced by secondary competing considerations such as personal gain.

References:

1. Lexchin J. "Interaction between physician and the pharmaceutical industry. What does the literature says?" *Canadian Medical Association Journal*, 1993; 149: 1401-1407
2. Shawn Caudill. T, Johnson. M. S, Rich. E. C, McKinney. P. "Physicians, Pharmaceutical Sales Representatives, and the Cost of Prescribing." *Family Medicine* 1996; 5(4):201-206
3. Rhee. J. "The Influence of the Pharmaceutical Industry on Healthcare Practitioners' Prescribing Habits." *The Internet Journal of Academic Physician Assistants* 2009; 7(1)
4. "How to manage conflicts of interest with industry?" *Int Rev Psychiatry*, April 2008 20:127- 133
5. Brennan. T. A, Rothman. D. J, Blank. L, Blumenthal. D, Chimonas. S. C, Cohen. J. J, Goldman. J, Kassirer, J. P, Kimball. H, Naughton. J, Smelser. N. "Health industry practices that create conflicts of interest: a policy proposal for academic medical centers." *JAMA* .Tan 25, 2006; 295(4): 429-433
6. Grant D. C, Iserson K. V. "Who's buying lunch: are gifts to surgeons from industry bad for patients?" *Thoracic Surgery Clinic*, November 2005; 15(4): 533- 542
7. J.T Chin. "Doctor-Patient Relationship: A Covenant of Trust". *Singapore Med J*, 2001,42 (12) : 579-581, accessed at <http://www.sma.org.sg/smj/4212/4212sf3.pdf>
8. Physician Payments Sunshine Act of 2009, Accessed at <http://www.govtrack.us/congress/hill.xpd?=&id=111-301>.
9. Wazana A. "Physicians and the pharmaceutical industry: is a gift ever just a gift?" *JAMA*, 2000, 283: 373-380.
10. Anthony-George D'Andrea. "Pharmaceutical Corruption" *Five Minutes to Midnight*, Sept 2004, 2 (9), Accessed at <http://i2r.org/fmm/issues/september2004/article1.html>

Useful Links

- Sonal Mehrotra, "Caught on camera: For bribes, doctors will prescribe you anything," *New Delhi Television Limited* (August 12, 2014) <http://www.ndtv.com/article/india/caught-on-camera-for-bribes-doctors-will-prescribe-you-anything-574334>.
- Michael ME Johns, Mark Barnes, Patrik S. Florencio, "Restoring balance to industry-academia relationships in an era of institutional financial conflicts of interest: promoting research while maintaining trust," vol. 289, no. 6 (2003): 741-746. <http://jamanetwork.com/journals/jama/article-abstract/195944>.
- Ashley Wazana, "Physicians and the pharmaceutical industry: is a gift ever just a gift?" vol. 283, no. 3 (2000): 373-380. <http://jamanetwork.com/journals/jama/article-abstract/192314>.
- Royal College of Physicians and Surgeons of Canada. Guidelines for support of continuing medical education by industry. http://rcpsctest.medical.org/english/public/policy/cme_e.html. Accessed December 8 1999. (Not accessible).
- Shaukat Ali Jawaid, Maqbool H. Jafary, "Relationship between the medical profession and the pharma industry: need for greater scrutiny, transparency and accountability," *Pakistan Journal of Medical Sciences*, vol. 20, no. 4 (2004): 283-291. <http://www.pjms.com.pk/issues/octdec04/pdf/article1.pdf>.
- Roy H. Perlis, Clifford S. Perlis, Yelena Wu, et al., "Industry sponsorship and financial conflict of interest in the reporting of clinical trials in psychiatry," *American Journal of Psychiatry*, vol. 162, no. 10 (2005): 1957-1960. http://ajp.psychiatryonline.org/doi/abs/10.1176/appi.ajp.162.10.1957?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed.
- Howard Brody, "The company we keep: why physicians should refuse to see pharmaceutical representatives," *The Annals of Family Medicine*, vol. 3, no. 1 (2005): 82-85. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1466797/pdf/0030082.pdf>.
- Nazim Ercument Beyhun, Cevriye Ceyda Kolayli, Gamze Can, et al., "Turkish final year medical students' exposure to and attitudes concerning drug company interactions: A perspective from a minimally regulated environment for medical students," *PloS one*, vol. 11, no. 12 (2016): e0168094. <http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0168094&type=printable>.
- David Grande, "Limiting the influence of pharmaceutical industry gifts on physicians: self-regulation or government intervention?" *Journal of General Internal Medicine*, vol. 25, no. 1 (2010): 79-83. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811591/pdf/11606_2009_Article_1016.pdf.
- Claudette Finley, "Gift-giving or influence peddling: can you tell the difference?" *Physical Therapy*, vol. 74, no. 2 (1994): 143-7.

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7: Human Subject Research Ethics

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WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimizes possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, and incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committee

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no

individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient- physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or

impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

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Useful Links

- Richard Cash, Daniel Wikler, Abha Saxena, et al., “Casebook on Ethical Issues in International Health Research,” *World Health Organization* (2009).
http://www.who.int/rpc/publications/ethics_casebook/en/.
- “International Ethical Guidelines for Biomedical Research Involving Human Subjects,” *Council for International Organizations of Medical Sciences (CIOMS) Guidelines* (2002).
http://www.cioms.ch/publications/layout_guide2002.pdf.
- The Nuremberg Code, *U.S. Department of Health & Human Services, Washington, D.C* (2015).
<http://wayback.archive-it.org/4657/20150930181802/http://www.hhs.gov/ohrp/archive/nurcode.html>.
- Nuffield Council on Bioethics Guidelines. <http://www.sirc.org/news/nuffield.shtml>.
- National Bioethics Committee guidelines for stem cell research.
http://nbcpakistan.org.pk/assets/guidelines_for_stem_cells.pdf.
- Sandra L. Alfano, "Conducting research with human subjects in international settings: ethical considerations," *The Yale Journal of Biology and Medicine*, vol. 86, no. 3 (2013): 315.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3767216/pdf/yjbm_86_3_315.pdf.
- David W. Dowdy, "Partnership as an ethical model for medical research in developing countries: the example of the “implementation trial”," *Journal of Medical Ethics*, vol. 32, no. 6 (2006): 357-360. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2563358/pdf/357.pdf>.
- Farhat Moazam, “Human subject research, ethics and the developing world,” *Journal Pakistan Medical Association*, vol. 50, no. 11 (2000): 388-92. <http://jpma.org.pk/PdfDownload/3209.pdf>.

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8: Public Health Ethics

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Case for Discussion

An influenza epidemic has begun in Pakistan confirmed by the World Health Organization (WHO) with some reported deaths. No one knows yet how serious the problem may be because there is no information on the extent of the outbreak. Large-scale public vaccination programs are not expected to be available for 8 to 12 weeks.

Public health officials are strongly recommending the immediate implementation of some restrictive measures to help slow the spread of the infection. This includes the cancelling of all large public gatherings. One family whose head is Mr. Raju and whose 2 teenage sons, 19-year-old Asif and 16-year-old Majid were killed in a car accident just as this information was released did not hear this information because it was disseminated in the media and they do not watch TV or listen to the radio. The family holds a funeral service of family and friends the following day. Over 70 people attend the funeral.

Public health authorities issue an order requiring everyone who attended the funeral to stay home for a period of 7 days, even though there is still little information about the virus or the extent of the outbreak. Mr. Raju wonders whether this is feasible, as his family depends on his income. He decides to go to work in the factory where he is employed while the rest of his family stays home.

The government has now declared a state of emergency. Three people who attended the funeral are showing symptoms of influenza and one person has died from it. Although Mr. Raju is aware that the outbreak has now hit close to home, he can't see how it would be possible for him not to go to work. After failing to heed the order, public health officials with help from the police detain Mr. Raju. His family is left with no income and stranded at home with little food.

Highlight the ethical issues in the above mentioned case.

What is your opinion of the public health authority's decision to detain Mr. Raju? Justify the position you take.

Do you think society has obligations to those ordered into quarantine? If so, elaborate on these.

"Principles of the ethical practice of public health," version 2.2,
Public Health Leadership Society (2002).
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Principles of the Ethical Practice of Public Health

Preamble

This code of ethics states key principles of the ethical practice of public health. An accompanying statement lists the key values and beliefs inherent to a public health perspective upon which the Ethical Principles are based. Public health is understood within these principles as what we, as a society, do collectively to assure the conditions for people to be healthy. We affirm the World Health Organization's understanding of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity.¹

The Code is neither a new nor an exhaustive system of health ethics. Rather, it highlights the ethical principles that follow from the distinctive characteristics of public health. A key belief worth highlighting, and which underlies several of the Ethical Principles, is the interdependence of people. This interdependence is the essence of community. Public health not only seeks to assure the health of whole communities but also recognizes that the health of individuals is tied to their life in the community. The Code is intended principally for public and other institutions in the United States that have an explicit public health mission. Institutions and individuals that are outside of traditional public health, but recognize the effects of their work on the health of the community, may also find the Code relevant and useful.

Values and Beliefs Underlying the Code

The following values and beliefs are key assumptions inherent to a public health perspective. They underlie the 12 Principles of the Ethical Practice of Public Health.

Health

1. *Humans have a right to the resources necessary for health.* The Public Health Code of Ethics affirms Article 25 of the Universal Declaration of Human Rights, which states in part "Everyone has the right to a standard of living adequate for the health and well-being of himself and his family"

Community

2. *Humans are inherently social and interdependent.* Humans look to each other for companionship in friendships, families, and community; and rely upon one another for safety and survival. Positive relationships among individuals and positive collaborations among institutions are signs of a healthy community. The rightful concern for the physical individuality of humans and one's right to make decisions for oneself must be balanced against the fact that each person's actions affect other people.

3. *The effectiveness of institutions depends heavily on the public's trust.* Factors that contribute to trust in an institution include the following actions on the part of the institution: communication; truth telling; transparency (i.e., not concealing information); accountability; reliability; and reciprocity. One critical form of reciprocity and communication is listening to as well as speaking with the community.

4. *Collaboration is a key element to public health.* The public health infrastructure of a society is composed of a wide variety of agencies and professional disciplines. To be effective, they must work together well. Moreover, new collaborations will be needed to rise to new public health challenges.

5. *People and their physical environment are interdependent.* People depend upon the resources of their natural and constructed environments for life itself. A damaged or unbalanced natural environment, and a constructed environment of poor design or in poor condition, will have an adverse effect on the health of people. Conversely, people can have a profound effect on their natural environment through consumption of resources and generation of waste.

6. *Each person in a community should have an opportunity to contribute to public discourse.* Contributions to discourse may occur through a direct or a representative system of government. In the process of developing and evaluating policy, it is important to discern whether all who would like to contribute to the discussion have an opportunity to do so, even though expressing a concern does not mean that it will necessarily be addressed in the final policy.

7. *Identifying and promoting the fundamental requirements for health in a community are of primary concern to public health.* The way in which a society is structured is reflected in the health of a community. The primary concern of public health is with these underlying structural aspects. While some important public health programs are curative in nature, the field as a whole must never lose sight of underlying causes and prevention. Because fundamental social structures affect many aspects of health, addressing the fundamental causes rather than more proximal causes is more truly preventive.

Bases for Action

8. *Knowledge is important and powerful.* We are to seek to improve our understanding of health and the means of protecting it through research and the accumulation of knowledge. Once obtained, there is a moral obligation in some instances to share what is known. For example, active and informed participation in policy-making processes requires access to relevant information. In other instances, such as information provided in confidence, there is an obligation to protect information.

9. *Science is the basis for much of our public health knowledge.* The scientific method provides a relatively objective means of identifying the factors necessary for health in a population, and for evaluating policies and programs to protect and promote health. The full range of scientific tools, including both quantitative and qualitative methods, and collaboration among the sciences is needed.

10. *People are responsible to act on the basis of what they know.* Knowledge is not morally neutral and often demands action. Moreover, information is not to be gathered for idle interest. Public health should seek to translate available information into timely action. Often, the action required is research to fill in the gaps of what we don't know.

11. *Action is not based on information alone.* In many instances, action is required in the absence of all the information one would like. In other instances, policies are demanded by the fundamental value and dignity of each human being, even if implementing them is not calculated to be optimally efficient or cost-beneficial. In both of these situations, values inform the application of information or the action in the absence of information.

Principles of the Ethical Practice of Public Health Principles of the Ethical Practice of Public Health

1. Public health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.

2. Public health should achieve community health in a way that respects the rights of individuals in the community.

3. Public health policies, programs, and priorities should be developed and evaluated through processes that ensure an opportunity for input from community members.
4. Public health should advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.
5. Public health should seek the information needed to implement effective policies and programs that protect and promote health.
6. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community's consent for their implementation.
7. Public health institutions should act in a timely manner on the information they have within the resources and the mandate given to them by the public.
8. Public health programs and policies should incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.
9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.
10. Public health institutions should protect the confidentiality of information that can bring harm to an individual or community if made public. Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.
11. Public health institutions should ensure the professional competence of their employees.
12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.

Rationale for a Public Health Code of Ethics Rationale for a Public Health Code of Ethics

The mandate to assure and protect the health of the public is an inherently moral one. It carries with it an obligation to care for the well being of others and it implies the possession of an element of power in order to carry out the mandate. The need to exercise power to ensure health and at the same time to avoid the potential abuses of power are at the crux of public health ethics. Until recently, the ethical nature of public health has been implicitly assumed rather than explicitly stated. Increasingly, however, society is demanding explicit attention to ethics. This demand arises from: technological advances that create new possibilities, and with them, new ethical dilemmas; new challenges to health such as the advent of human immunodeficiency virus; abuses of power, such as the Tuskegee study of syphilis; and an increasingly pluralistic society in which we can no longer simply adopt the values from a single culture or religion, but we must work out our common values in the midst of diversity. Historically, medical institutions have been more explicit about the ethical elements of their practice than have public health institutions. The concerns of public health are not fully consonant with those of medicine, however, thus we cannot simply translate the principles of medical ethics to public health. For example, in contrast to medicine, public health is concerned more with populations than with individuals, and more with prevention than with cure. Thus, the purview of public health includes those who are not presently ill, and for whom the risks and benefits of medical care are not immediately relevant.

What Does a Code of Ethics Accomplish?

A code of ethics for public health clarifies the distinctive elements of public health and the ethical principles that follow from or respond to those distinct aspects. It makes clear to populations and

communities the ideals of the public health institutions that serve them. A code of ethics thus serves as a goal to guide public health institutions and practitioners and as a standard to which they can be held accountable.

Codes of ethics are typically relatively brief; they are not designed to provide a means of untangling convoluted ethical issues. That process requires deliberation and debate over the multitude of factors relevant to a particular issue. Nor does a code typically provide a means of resolving a particular dispute. It does, however, provide those in a dispute over a public health concern with a list of issues and principles that should be considered in the dispute.

Rationale for a Public Health Code of Ethics Rationale for a Public Health Code of Ethics

A Living Document

Many public health professionals, most of them associated with the Public Health Leadership Society (PHLS), came together to initiate the process of writing the Code. Represented on the PHLS Public Health Code of Ethics Committee are public health professionals from local and state public health, public health academia, the Centers for Disease Control and Prevention (CDC), and the American Public Health Association (APHA). They were formally encouraged in this effort during a town hall meeting attended by representatives from a wide variety of public health organizations at the 2000 APHA annual meeting. A draft code was reviewed and critiqued in May 2001 by 25 public health professionals and ethicists in a CDC-funded meeting held in Kansas City. A revised version of the Code was presented for discussion at another town hall meeting at the 2001 APHA annual meeting. Prior to the meeting, the Code was published on the APHA Website and an e-mail address was provided for reactions and feedback. The present code reflects the input and discussion from all of these forums. It is now being presented to various organizations for adoption or endorsement. Even so, there are ongoing opportunities to provide feedback (see page 10 for details), and an updating of the Code is anticipated. Tools for teaching about the Code and ensuring its practical utility are currently in the making.

Notes on the Individual Ethical Principles

1. This Principle gives priority not only to prevention of disease or promotion of health, but also at the most fundamental levels. Yet the principle acknowledges that public health will also concern itself with some immediate causes and some curative roles. For example, the treatment of curable infections is important to the prevention of transmission of infection to others. The term “public health” is used here and elsewhere in the Code to represent the entire field of public health, including but not limited to government institutions and schools of public health.

2. This Principle identifies the common need in public health to weigh the concerns of both the individual and the community. There is no ethical principle that can provide a solution to this perennial tension in public health. We can highlight, however, that the interest of the community is part of the equation, and for public health it is the starting place in the equation; it is the primary interest of public health. Still, there remains the need to pay attention to the rights of individuals when exercising the police powers of public health.

3. A process for input can be direct or representative. In either case, it involves processes that work to establish a consensus. While democratic processes can be cumbersome, once a policy is established, public health institutions have the mandate to respond quickly to urgent situations. Input from the community should not end once a policy or program is implemented. There remains a need for the community to evaluate whether the institution is implementing the program as planned and whether it is having the intended effect. The ability for the public to provide this input and sense that it is being heard is critical in the development and maintenance of public trust in the institution.

4. This Principle speaks to two issues: ensuring that all in a community have a voice; and underscoring that public health has a particular interest in those members of a community that are underserved or marginalized. While a society cannot provide resources for health at a level enjoyed by the wealthy, it can ensure a decent minimum standard of resources. The Code cannot prescribe action when it comes to ensuring the health of those who are marginalized because of illegal behaviors. It can only underscore the principle of ensuring the resources necessary for health to all. Each institution must decide for itself what risks it will take to achieve that.

5. This Principle is a mandate to seek information to inform actions. The importance of information to evaluate programs is also implied.

6. This Principle is linked to the third one about democratic processes. Such processes depend upon an informed community. The information obtained by public health institutions is to be considered public property and made available to the public. This statement is also the community-level corollary of the individual-level ethical principle of informed consent. Particularly when a program has not been duly developed with evaluation, the community should be informed of the potential risks and benefits, and implementation of the program should be premised on the consent of the community (though this principle does not specify how that consent should be obtained).

7. Public health is active rather than passive, and information is not to be gathered for idle interest. Yet the ability to act is conditioned by available resources and opportunities, and by competing needs. Moreover, the ability to respond to urgent situations depends on having established a mandate to do so through the democratic processes of Ethical Principle number three.

8. Public health programs should have built into them a flexibility that anticipates diversity in those needs and perspectives having a significant impact on the effectiveness of the program. Types of diversity, such as culture and gender, were intentionally not mentioned. Any list would be arbitrary and inadequate.

9. This Principle stems from the assumptions of interdependence among people, and between people and their physical environment. It is like the ethical principle from medicine, “do no harm,” but it is worded in a positive way.

10. This statement begs the question of which information needs to be protected and what the criteria are for making the information public. The aims of this statement are modest: to state explicitly the responsibility inherent to the “possession” of information. It is the complement to Ethical Principles 6 and 7, about acting on and sharing information.

11. The criteria for professional competence would have to be specified by individual professions, such as epidemiology and health education.

12. This statement underscores the collaborative nature of public health while also stating in a positive way the need to avoid any conflicts of interest that would undermine the trust of the public or the effectiveness of a program.

Correspondence of the 12 Ethical Principles with the 10 Essential Public Health Services

Essential Public Health Services 2	Ethical Principle
1. Monitor the health status to identify community health problems	(5) collect information (7) act on information
2. Diagnose and investigate health problems and health hazards in the community	(5) collect information
3. Inform, educate, and empower people about	(4) advocacy and empowerment

health issues	(6) provide information
4. Mobilize community partnerships to identify and solve health problems	(12) collaboration
5. Develop policies and plans that support individual and community health efforts	(1) protect and promote health; address fundamental causes of health risks (3) processes for community input (5) collect information
6. Enforce laws and regulations that protect health and ensure safety	(2) achieve community health with respect for individual rights (3) feedback from the community (7) act upon information
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable	(4) advocate for and empower; basic resources available to all (8) incorporate diversity
8. Assure a competent public health and personal health care workforce	(11) professional competence
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services	(3) community feedback (5) collect information
10. Research for new insights and innovative solutions to health problems	(5) collect information
No corresponding essential public health service	(9) enhance physical and social environments (10) protect confidentiality

Contact for Further Information and Feedback

Visit www.phls.org for:

- Ways to provide feedback to inform ongoing development of the 12 Ethical Principles
- Information on aligning your organization’s public health practice with the 12 Ethical Principles
- Permission to reprint the 12 Ethical Principles and supporting documentation
- Requests for further information about public health ethics or the Public Health Leadership Society
- Public Health Leadership Society contact information

Acknowledgements

The development and dissemination of the Principles of the Ethical Practice of Public Health is funded by a cooperative agreement between the Centers for Disease Control and Prevention and the Public Health Leadership Society (PHLS). The Center for Health Leadership & Practice, Public Health Institute is acknowledged for its role in the initial development of the Principles. PHLS also acknowledges the work of the members of the original PHLS Ethics Work Group (responsible for drafting the Code) and the current members of the PHLS standing Committee on Public Health Ethics. Specifically, PHLS acknowledges the following contributors: Elizabeth Bancroft (Centers for Disease Control and Prevention, Los Angeles County), Terry Brandenburg (West Allis Health Department), Kitty Hsu Dana (American Public Health Association), Jack Dillenberg (Arizona School of Health Sciences), Joxel Garcia (Connecticut Department of Health), Kathleen Gensheimer (Maine Department of Health), V. James Guillory (University of Health Sciences, Kansas City, MO), George Hardy (Association of State and Territorial Health Officers), Joseph Kimbrell (Louisiana Public Health Institute and National Network of Public Health Institutes), Teresa Long (Columbus, OH, Department of Health), Alan Melnick (Oregon Health and Science University, School of Medicine), Susan Myers (University of Pittsburgh), Ann Peterson (Virginia Department of Health), Michael Sage (Centers for Disease Control and Prevention), Margaret Schmelzer (Wisconsin Department of Health and Family Services), Liz Schwarte (Center for Health Leadership & Practice, Public Health Institute), James Thomas (University of North Carolina),

Kathy Vincent (Alabama Health Department), and Carol Woltring (Center for Health Leadership and Practice, Public Health Institute).

Useful Links

- Nancy E. Kass, "An ethics framework for public health," *American Journal of Public Health*, vol. 91, no. 11 (2001): 1776-82.
<http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.91.11.1776>.
- Carl, H. Coleman, Bouësseau Marie-Charlotte, Reis Andreas, "The contribution of ethics to public health," *WHO Bulletin* 8 (2008): 577-656. <http://www.who.int/bulletin/volumes/86/8/08-055954/en/>.
- "Public health: ethical issues," *Nuffield Council on Bioethics* (2007).
<http://nuffieldbioethics.org/wp-content/uploads/2014/07/Public-health-ethical-issues.pdf>.
- Steven S. Coughlin, "Ethical issues in epidemiologic research and public health practice," *Emerging Themes in Epidemiology*, vol. 3, no. 1 (2006): 16.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1594564/pdf/1742-7622-3-16.pdf>.

9: Plagiarism and Scientific Misconduct

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7	Jamshed Akhtar, "Plagiarism: What authors need to know," <i>Journal of Surgery Pakistan, International</i>," vol. 13, no. 1 (2008): 1	332
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Cases for Discussion

- **Case 1**

In a manuscript which has five authors, which of the following is correct –

1. The names of the authors should be listed alphabetically
2. The names should be listed according to the contribution of each author. The person with major contributions should be the first author, and so on.
3. The names should be listed as per seniority and the head of the department or institution should be the first author.

- **Case 2**

You have received a manuscript with eight authors who include one pathologist and two third year medical students. The study has been conducted by faculty members of an undergraduate medical college.

1. Will you accept it as such with all the listed authors?
2. Should the corresponding author be asked to provide the individual contributorship of each author?
3. Should the corresponding author be asked to reduce the authors to those with contributions to the research and the manuscript, and list others in the acknowledgement section?

- **Case 3**

The editor-in-chief of a journal insists that authors include references from his journal in their articles. He provides examples from other journals in the field which do so as evidence that it is a standard and acceptable practice. Some authors however do not agree and believe that this is an unethical demand of the journal.

Do you think this practice by editors is justifiable or not?

Reference

1. Some of these conundrums have been adapted from real-life case studies published on the COPE website: <http://www.publicationethics.org> (after some modification).

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Teaching Video

Publish or Perish: <https://vimeo.com/51499635>

This movie highlights several areas of scientific misconduct that can tempt researchers, driven by increasing pressures to publish research work in order to move up the academic ladder. Viewers will notice examples of plagiarism, fudging data, gifted authorship and other similar issues highlighted in this film. The film ends by touching the issue of whistle blowing.

Common Terms and Concepts

(Provided by Shaukat Ali Jawaid)

Common Terms and Concepts

Definition:

Plagiarism is defined as stealing someone else's ideas, thoughts or work without giving due credit to that person. It can also be defined as "theft of someone else's ideas and concepts and pretending that they are your own."

Another definition of plagiarism is "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. One form is the appropriation of the ideas and results of others, and publishing as to make it appear the author had performed all the work under which the data was obtained.

Types of Plagiarism¹

Word for Word: Word for word plagiarism is copying and pasting without complete and proper referencing.

Mosaic: Mosaic means cut and paste from different sources.

Paraphrasing: Paraphrasing and summarizing others' work, if not properly referenced also amounts to plagiarism.

Cyber Plagiarism: Copying ideas found on the web if not given proper attribution is known as cyber plagiarism.

Forms of Plagiarism

Citation Plagiarism: Willful or negligent failure to appropriately credit other or prior discoverers, so as to give an improper impression of priority. This is also known as, "citation amnesia", the "disregard syndrome" and "bibliographic negligence" Arguably, this is the most common type of scientific misconduct. Sometimes it is difficult to guess whether authors intentionally ignored a highly relevant cite or lacked knowledge of the prior work. Discovery credit can also be inadvertently reassigned from the original discoverer to a better- known researcher.

Plagiarism-Fabrication: The act of taking an unrelated figure from an unrelated publication and reproducing it exactly in a new publication (claiming that it represents new data). Recent papers from the University of Cordoba have come to light showing how this can go undetected and unchallenged for years.

Plagiarism can have very serious consequences for the authors which include loss of job, demotion, retraction of publication, loss of reputation and fine. The journals can take actions against authors whose articles are plagiarized by retracting the publication or may also blacklist the author for future works. Plagiarism is a crime; it is unethical and unacceptable in any form.

Self-plagiarism: Multiple publications of the same content with different titles and/or in different journals is sometimes also considered misconduct; scientific journals explicitly ask authors not to do this.

It is referred to as “salami” (i.e. many identical slices) in the jargon of medical journal editors (MJE). According to some MJE this includes publishing the same article in a different language.

The basis of science is honesty, but to lessen the work load of scientific research, researchers find plagiarism an easy solution to the problem. It is scientific misconduct which is made easy today due to the convenient access to internet, journals and libraries.

Authors plagiarize due to laziness, pressure to publish, ambitiousness and inability to write especially not having a command on the English language. People with low ethical standards always look out for a shortcut.

Softwares to Check Plagiarism

Many softwares are available to check plagiarism. Some of them are freely available on the net while others have to be subscribed. Most of the biomedical journals use either TURNITIN or CrossCheck for which one has to pay while eTblast is available free.

1. TURNITIN
2. CrossCheck
3. eTblast

Types of Scientific Misconduct

(Provided by Shaukat Ali Jawaid)

Appendix (b) Section 17

Types of Scientific Misconduct

Duplicate Publication: Publishing the same manuscript/study with little or no modification in another journal once it has already been published. Duplicate publication of same results is increasing since the authors are under pressure to publish more.

Scientific Misconduct: It is the violation of the standard codes of scholarly conduct and ethical behavior in professional scientific research.

Danish Definition: "Intention or gross negligence leading to fabrication of the scientific message or a false credit or emphasis given to a scientist"

Swedish Definition: "Intentional distortion of the research process by fabrication of data, text, hypothesis, or methods from another researcher's manuscript form or publication; or distortion of the research process in other ways."²

The consequences of scientific misconduct can be damaging for both perpetrators and any individual who exposes it. In addition there are public health implications attached to the promotion of medical or other interventions based on dubious research findings.

Fabrication: Making up of data or results. Yet another definition of fabrication is making up results and recording or reporting them. This is sometimes referred to as "drylabbing". A more minor form of fabrication is where references are included to give arguments the appearance of widespread acceptance, but are actually fake, and/or do not support the argument. Falsification is manipulating research materials, equipment, or processes or changing or omitting data or results such that the research is not accurately represented in the research record.

Fabrication of Data: It is less common than plagiarism. But it is still not uncommon. An important case of fabrication is the Hwang Woo-Suk of South Korea who fabricated the results of stem-cell lines and he claimed to have created and claimed to have successfully created human embryonic stem cells by cloning. There is bias towards positive result and lack of publication of negative data. As such researchers inevitably trend towards positive findings rather than negative.

Research publications enterprise is based on Trust. Inculcation of responsible conduct among young researchers and authors should be the key concern for academic mentors and editors. For a long time Research enjoyed immunity from accountability. Now we see blemished image of medical research.

Falsification: Manipulating research material, equipment or process.

In addition, some academics consider suppression the failure to publish significant findings due to the results being adverse to the interests of the researcher or his/her sponsor(s)—to be a form of misconduct as well.

Academic Misconduct: It is defined as any action or attempted action that may result in creating an unfair academic advantage for oneself or an unfair academic advantage or disadvantage for any other member or members of the academic community.³

Salami Slicing : It refers to a series of many small actions, often performed by clandestine means, that as an accumulated whole produces a much larger action or result that would be difficult or unlawful to perform all at once. The term is typically used pejoratively. Although salami slicing is often used to carry out illegal activities, it is only a strategy for gaining an advantage over time by accumulating it in small increments, so it can be used in perfectly legal ways as well.

ICMJE Guidelines on Authorship

Plagiarism and Scientific Misconduct

(Provided by Shaukat Ali Jawaid)

Appendix (c) Section 17 ICMJE Guidelines on Authorship⁴

As per International Committee on Medical Journal Editors (ICMJE) guidelines the authorship should be based on the following criteria:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be published.
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All those who meet the above four conditions are eligible to be included as Authors in the manuscript.

Multicenter Group: When a large multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributor ship defined above and the Editors should ask these individuals to complete journal specific author and conflict of interest disclosure forms.

Group Author Manuscripts: When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals should generally enlist other members of the group in acknowledgement.

ICMJE guidelines further state that acquisition of funding, collection of data, general supervision of the research group does not qualify any one to be an author. Similarly all persons designated as authors should qualify for authorship and all those who qualify should be listed. It is also important that each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Acknowledgement: All contributors who do not meet the criteria for authorship should be listed in an acknowledgment section. Those who provide technical support, writing assistance, or a department chair who provided just general support should be mentioned in acknowledgment. It is also important that all those whose names appear in acknowledgement must have given permission to be acknowledged as the readers might infer their endorsement of the data and conclusions.

Authorship Issues

Gift Authorship: A practice in which senior researchers are listed as co-authors despite having had little to do with the work involved in publishing original research reports or research reports that are the works of others, e.g., undergraduates and postdoctoral fellows working in their lab.⁵

Ghost Authors: “One who secretly does artistic or literary work for another person, the latter taking the credit” (Frank Place, Librarian New York Academy of Medicine, New York 1934).

Summary: “The Ghost or paid literary worker has been and will be a necessary help for busy physicians in preparing papers and other literary material. Instead of being condemned for mistakes in the past the ghost is to be encouraged, and authors are well advised in acknowledging assistance rendered by him.”⁶

White Ghosts: Reviewers, medical ethics committees, colleagues, English editors. They can influence the final shape of contents of a paper. It includes Editors, Reviewers, Medical Ethics Committees, Colleagues, Feedback from seminars etc., Supervisors and Nellig Editors.

Grey Ghosts: Medical writers, professional communicators. Industry funding, controlled or advised studies can result in industry favorable outcomes. Outcome is variable and may simply improve the quality of the manuscript.

Black Ghosts: Medical writing promoters (Pharma), for profit “throwaways” these black ghosts’ influence the final content of a paper changes or reduces the accuracy of all or some of the scientific conclusions of the paper. (Pharma, food industry).⁷⁻⁹

Addition of Authors after Acceptance of Manuscript: It should not be permitted. However if during revision of the manuscript the authors have taken help and assistance from others they can be allowed to be added as authors.

References

1. Liz Wager. How should editors respond to plagiarism? COPE Discussion Paper April 2011. www.publicationethics.org.uk.
2. Scientific misconduct (Danish & Swedish definition) URL: http://en.wikipedia.org/wiki/Scientific_misconduct.
3. Division of student conduct. The centre for student conduct. [Internet]. Barkeley university of California; [cited 2013 March 31] Available from: <http://sa.berkeley.edu/conduct/integrity/definition>.
4. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. Revision 2010. Available from: www.icmje.org/urm_main.html (Accessed April 18, 2013).
5. Segen's Medical Dictionary. © 2012 Farlex, Inc.
6. Frank Place, Librarian New York Academy of Medicine, New York USA.2012.
7. Waxman HA JD. The lessons of Viovox. Drug Safety and Sales. New Eng J Med 2005; 352(25):2576-2578.
8. Jawaid SA. Proceedings of APAME Congress 2012 held at Kuala Lumpur Malaysia (August 31st to September 2nd 2012) Pak J Med Sci 2012; 28(5):979-987.
9. Jawaid SA. Proceedings of First International meeting of Research Journal Editors organized by Islamic World Science Citation Center at Shiraz, Iran (October 23-24th 2012) Pak J Med Sci 2013;29(1):242-248. doi:<http://dx.doi.org/10.12669/pjms.291.3181>.

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Bushra Shirazi, Aamir M. Jafarey, Farhat Moazam, "Plagiarism and the medical fraternity: a study of knowledge and attitudes," *The Journal of the Pakistan Medical Association*, vol. 60, no. 4 (2010): 269-273.
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Plagiarism and the Medical Fraternity: A Study of Knowledge and Attitudes

Bushra Shirazi, Aamir M. Jafarey, Farhat Moazam

Abstract

Objective: To assess knowledge and perceptions of plagiarism in medical students and faculty of private and public medical colleges in Karachi.

Methods: A questionnaire based study was conducted on groups of 4th year medical students and medical faculty members. Group A consisted of medical students while group B comprised faculty members. The questionnaire contained 19 questions that assessed knowledge and attitudes of the respondents regarding various aspects of plagiarism.

Results: The total number of medical students (Group A) studied was 114 while the faculty number (Group B) was 82. Nineteen percent Group A and 22% of Group B displayed the correct knowledge about referencing materials from the internet or other sources. Seventeen percent of respondents in Group A and 16% in Group B had correct information about the use of quotation marks when incorporating verbatim phrases from external sources. Regarding Power Point presentations, 53% of respondents from Group A and 57% from Group B knew the appropriate requirements. There was a statistically significant difference among the two groups regarding the issue of self plagiarism, with 63% of respondents in Group A and 88% in Group B demonstrating correct understanding. Both groups showed a general lack of understanding regarding copyright rules and 18% of Group A and 23% of respondents in Group B knew the correct responses. Eighteen percent of respondents in Group A and 27% in Group B claimed to have never indulged in this practice.

Conclusion: There is a general lack of information regarding plagiarism among medical students and faculty members (JPMA 60:269; 2010).

Introduction

The term plagiarism can be traced to Marcus Valerius Martialis (died 103 AD) who first employed it for the theft of intellectual material without acknowledging the source.¹ Intellectual theft includes theft of ideas, works from literature and science, reports, assignments or presentations. Easy access to a vast pool of electronic resources has made plagiarism all the more easy and within reach of anyone with a computer with internet access. Various reasons can be ascribed for indulging in plagiarism including a fiercely competitive academic milieu, impossible deadlines and an increasingly hostile environment fostering a "publish or perish" culture. Judging by reports, plagiarism appears to be a common issue in academic institutions across the world and is increasingly being reported from many Pakistani institutions as well.

The issue of plagiarism has been taken up vigorously by the news media also and several editorials have appeared in recent months highlighting the issue.² The extent of the problem can be gauged by the fact

that faculty members of a reputable university have been reported charging each other of plagiarism.³ An apparent lack of emphasis by institutions in highlighting the problem has been quoted as one of the major reasons for rampant plagiarism.⁴

Apart from sporadic news reports and editorials, there is no scientific data analyzing the issue available from within Pakistan. It has therefore not been possible to understand the true nature and extent of the problem in this country.

One of the main motivations for this pilot study was based on personal experience of two of the authors of this paper. While assessing essays submitted as a requirement for admission into a bioethics diploma programme, they noticed an alarming number of plagiarized submissions. Upon questioning the offending applicants, it appeared that most of them genuinely did not believe they had plagiarized their work and insisted that they had only attempted to strengthen their work with "research" from the internet. This level of ignorance about such an important aspect of scientific research and writing, and that too from mid career medical professionals, was of significant concern. This study was undertaken as a pilot, to gain a better understanding about plagiarism in the local context and to explore perceptions about various stakeholders on the issue.

Subjects and Methods

Between May and September 2008, a questionnaire based study was conducted in Karachi on selected groups of 4th year medical students and medical faculty members. Using convenience sampling, this interviewer led study involved participants from one government and two private sector medical colleges in the city.

A questionnaire, consisting of 19 detailed questions, was developed to assess knowledge and attitude of respondents about various forms of plagiarism and related issues such as copyright laws. This article presents a selection of results from the survey which we believe as most important to the prevailing situation in Pakistan. Portion of the questionnaire included in this paper are reproduced in Table-1.

Using a uniform system, two of the authors administered the questionnaire in selected medical institutions to groups of 4th year medical students at the end of regularly scheduled classes. This particular level of students was chosen for the sake of convenience since one of the authors had direct access to this group at her institution. Similar level students were selected at all three survey sites to maintain participant uniformity. Of the three institutes, one was from the government and two from the private sector. After explaining the objectives of the study and obtaining a verbal informed consent, each question was read out aloud and participants given time to write their responses before moving on to the next question. Consenting groups of medical faculty were similarly surveyed using the same methodology following multidisciplinary academic meetings. Faculty participants included a mix of junior and senior consultants from the disciplines of Basic Biomedical Sciences, Internal Medicine, General Surgery, Urology, Obstetrics and Gynaecology, Paediatrics, and Neurology. To encourage frank answers, participants were assured of anonymity and only their specialty and institutional affiliation were recorded.

Following completion and collection of questionnaires from each group, a brief educational session was conducted for participants to discuss various aspects of plagiarism along with a questions and answers session to clarify any confusion about the subject.

The responses were assessed against a pre-formed correct response key and the main outcome measure was the level of correlation between the responses to various questions and the key. A response indicated adequate knowledge of the respondent if the response matched the key.

The study was reviewed and approved by the Ethical Review Boards of the institutions in which it was conducted.

Results

The total number of medical students (Group A) studied was 114 while the faculty number (Group B) was 82. Overall, only 22 respondents (19%) in Group A and 18 (22%) in Group B had appropriate knowledge about standard referencing criteria incorporation into one's work.

Table-1: Questionnaire

<p>Select the appropriate answer, more than one may be correct (correct responses are highlighted).</p> <p>(1) While accessing information from internet based source, is it acceptable to:</p> <ul style="list-style-type: none">a) Cut and paste the relevant portions<ul style="list-style-type: none">i) Within quotationsii) With reference to the original sourceb) Paraphrase the relevant portion and<ul style="list-style-type: none">i) Within quotationsii) With reference to the original source <p>(2) Regarding what material requires to be referenced in your paper:</p> <ul style="list-style-type: none">a) All the material that is used in your paper needs to be referenced.b) Well known facts (e.g. Islamabad is the capital of Pakistan) require to be referenced.c) The material that is used as a direct quote should be referenced.d) Only material from printed sources needs referencing.e) Since this is a paper for institutional use only, there is no need for referencing anything. <p>(3) Is it acceptable to access a relevant presentation, cartoon/ pictures/video clips available easily on web and:</p> <ul style="list-style-type: none">a) Use it as it is, without modification<ul style="list-style-type: none">i) Reference the original sourceii) Not include any reference as no copy rights mentionedb) Modify and use it<ul style="list-style-type: none">i) Reference the original sourceii) Not include any reference as no copy rights mentionedc) Reference only material that has a copy right symbold) Not use any material that has copyright symbol ©e) Not use anything from the internet <p>(4) Have you ever plagiarized</p> <p>(5) Did you take any action if you noticed a colleague of your plagiarize</p>
--

Table-2: Results.

#	Area assessed	Group A	Group B	P-Value
1	Correct understanding for need for referencing	n=22(19%)	n=18(22%)	0.73
2	Correct understanding of methodology for incorporating materials as paraphrases	n=49(43%)	n=44(54%)	0.16
3	Correct understanding of methodology for incorporating	n=19(17%)	n=13(16%)	0.99
4	Correct understanding of methodology for incorporating web based clips/cartoons in their own PowerPoint	n=55(48%)	n=37(45%)	0.78
5	Correct understanding of methodology for incorporating PowerPoint presentations available on the web	n=60(53%)	n=47(57%)	0.68
6	Correct understanding of the concept of self plagiarism	n=72(63%)	n=72(88%)	0.01
7	Correct understanding of the concept of copyrights	n=21(18%)	n=19(23%)	0.49
8	Never plagiarized work themselves	n=21(18%)	n=22(27%)	0.18
9	Have observed colleagues plagiarize work	n=84(74%)	n=56(69%)	0.54
10	Took action against plagiarists	n=12(10%)	n=11(13%)	0.66

Forty nine (43%) respondents in Group A and 44 (54%) in Group B gave correct answers regarding appropriate methodology for incorporating paraphrased material into their work. Even more strikingly, only 19 (17%) people in Group A and 13 (16%) in Group B had correct information about the use of quotation marks when incorporating verbatim phrases from books and journals.

Medical students and faculty displayed insufficient knowledge, with little difference between the two groups, regarding the use of web based materials including ready made presentations, clips and cartoons (Table-1).

When respondents were assessed on their understanding of self-plagiarism, 72 (63%) of Group A and 72 (88%) of group B respondents gave correct answers. This was the only area where there was a statistically significant ($p < 0.01$) difference in the responses of the two groups. In contrast, only 20 (18%) and 19 (23%) respondents in Group A and Group B respectively demonstrated correct understanding about the concept of copyrights.

Ensuring anonymity of participant identity, we also attempted to explore personal attitudes towards plagiarism. A majority from both groups admitted to having plagiarized material at one time or the other. Moreover, 84 (74%) of Group A respondents and 56 (69%) in Group B reported knowing of a colleague who had plagiarized work while only a very small number from both groups stated that they had taken steps for action against the plagiarist, but our study did not include questions about the nature of steps taken (Table-1).

Discussion

To the best of the authors' knowledge, this is the first study of its kind in Pakistan analyzing the issue of plagiarism. Although limited to Karachi, it sheds light on the nature and extent of the problem that afflicts academia and the student body in Pakistan. The results of our study, although conducted in three institutions of Karachi, are however reflective of the extent of a problem that exists countrywide within

our medical communities. Answers to our questionnaire, turned in anonymously, revealed that more than half of the respondents lacked knowledge about some of the most basic principles that constitute plagiarism. Even more concerning, but logical, was our finding that this paucity of knowledge appeared to be equally distributed among medical students and the medical faculty responsible for their education. It was only in the area of self plagiarism where faculty displayed better understanding than students perhaps due to their experience with prior publications.

Roughly only half of the medical students and faculty in this study knew the requirements for correctly referencing and citing material from written sources whether used in the form of a paraphrase or as direct, verbatim quotes. This was no different from the low level of knowledge about the correct use of web based material, including clips and cartoons, for Power Point presentations. Information was especially low in both groups (Group A 17%, Group B 16%) when it came to proper usage of quotation marks for verbatim portions obtained from published sources to distinguish these from their own words in the written text. Our survey findings lead us to believe that neither group has had the benefit of receiving appropriate education about what constitutes plagiarism, an increasingly complex issue with the explosion of easily available internet sources, and that this lack of knowledge may be a major underlying cause of this problem in Pakistan.

Plagiarism is becoming an increasing concern around the world and we believe there may be multiple causes behind this practice. In a 2007 study from Florida by Forrester, 56% of medical students were reported to have copied material word for word providing references but without using quotation marks.⁵ Our study however reveals this lack of knowledge about the need for quotation marks also among faculty members, leading us to speculate that this form of plagiarism may be inadvertent rather than done consciously. However authors reporting a study done in Croatia suggest that in countries where the national language is not English and command over it is poor, people may be more inclined to include materials verbatim without delineating them in quotation marks.⁶

A majority of the respondents from both groups in our study confessed to have indulged in plagiarism themselves and also to have known their colleagues to plagiarize their work at one time or the other. Among our participants, 18% of group A and 27% of group B claimed to have never plagiarized. Plagiarism is of course not unique to Pakistan and researchers from countries within developing and developed regions of the world have reported cases of plagiarism occurring in schools and universities. In one study on dental students in Iowa, 43% of students admitted to cheating at least once.⁷ In another study from Croatia looking at the prevalence of plagiarism among medical students, only 9% of students were found to have never been involved in this practice.⁸

Although no previous studies such as ours have been carried out in Pakistan, newspapers have been reporting increasing instances of cheating among students. Some note this to be occurring as early as in secondary school levels and some teachers have been found justifying the use of unfair means by students in order to pass annual examinations.⁹ We suspect that societal nonchalance towards using unfair means to ensure success in examinations is leading to increasing tolerance towards plagiarism. This may help to provide an explanation for our disconcerting finding that even when participants observed someone plagiarizing, only a few considered this important enough to take an action against the offender (10% and 13% of Groups A and B respectively). This failure to act on the part of the majority reflects a growing tolerance towards plagiarism leading to internalization and acceptance of clearly unethical academic conduct.

Other factors may also be responsible for reluctance to report incidences of plagiarism. In a study from the Middle East exploring attitudes towards academic integrity, utilizing a self-administered questionnaire to medical students and interns, plagiarism was seen by many as a minor offense when compared to misuse of authority and power. When it came to reporting misconduct, many students believed that this

was not their responsibility, and also feared repercussions from peers if they were to do so. Our suspicion that our study suggests increasing tolerance for plagiarism is supported by the Middle Eastern study in which participants reported that "everyone else is doing it."¹⁰

The fact that both students and faculty in our study had poor knowledge about copyright laws, with the latter scoring only marginally better than the former, is of obvious concern. It has been suggested that due to the high cost of obtaining copyrighted educational material in developing countries, some do not consider it morally objectionable to infringe copyright laws. The justification commonly given by people is that without doing so even seminal works in different disciplines are beyond the reach of students from less affluent countries. This is not an area we explored in our study but one that requires further investigation in Pakistan.

There appears to be no international consensus on the punitive actions to be taken against students, faculty, and professionals who plagiarize. A study from Canada involving dental faculty and students reveals opinions varying from verbal reprimands to failing students in a semester if caught plagiarizing.¹¹ There are some examples of severe professional consequences for plagiarists. In England, a well known psychiatrist was suspended for three month because of plagiarism, a punishment he claimed to be out of proportion to his offence.¹² In USA, cases have been reported of expulsion and dismissal of students and professors from institutions including Harvard University.¹³

In Pakistan, although the Higher Education Commission (HEC) does not provide a uniform policy for punishing plagiarists, it does offer a set of broad guidelines for institutions. This is in the form of a "Little Book of Plagiarism," a document adapted from guidelines of the Leeds Metropolitan University.¹⁴ In addition to providing the definition of plagiarism and describing its different forms, the document also suggests punitive measures that may be taken against offenders. A wide variation however exists on this matter among educational and administrative groups in Pakistan. Recent events in the Punjab University (PU) are a case in point. When it was determined that some PU teaching faculty had been involved in plagiarism, the PU Syndicate decided to let the offenders off with little more than a warning although HEC had recommended their dismissal. The Syndicate's action however led to an uproar prompting HEC to put a hold on PU grants, and the ensuing tussle reflected the divergence of opinions on this matter within academic circles.^{15, 16} Moreover, with the recent cutback in Pakistan government's funding for HEC, and thus a curtailment of its grants giving powers, it remains to be seen whether its attempts to enforce strict action against plagiarists within universities in Pakistan can continue.¹⁷

There are sufficient reasons to believe that plagiarism within Pakistani academic institutions is commonplace rather than a rarity. Our study suggests that in many cases this may be due to lack of information and education, rather than malice, on the part of students and faculty as to what constitutes plagiarism. We believe this to be an area that must be addressed through education, and on an urgent basis. Institutions must also assume a zero tolerance policy towards plagiarism; make this policy well known to students, faculty and staff, and deal promptly and decisively with those who deliberately breach this policy. Plagiarism detection software must also be made available to universities and teaching institutions. Until recently HEC provided services of an online plagiarism detection site free of cost to public institutions. This free facility was withdrawn this year due to lack of funding, and it is highly unlikely that many institutions will be able to afford the subscription fee now required by HEC for this service.

Conclusions and Recommendations

The results of this study suggest that a major reason for plagiarism in the medical fraternity is because both medical college teachers and the students share a high level of ignorance regarding the issue. They simply do not know that they are plagiarizing. The study however also indicates a degree of apathy. Even among those who do have some awareness about the issue admit to have plagiarized their work at one

time or the other. Furthermore, there is also a noticeable level of general reluctance to report this offense to the authorities.

The level of complacency demonstrated in this study is of concern, especially so because it seems to have been effectively transferred down the generation. This study provides enough evidence to warrant a greater, in depth look at plagiarism around the country. There is also a dire need to devise an educational strategy aimed at raising awareness of individuals and institutions about plagiarism. Additionally, institutions need to evolve policies to detect and counter this menace, provide practical guidelines to its personnel and empower them by providing education in this important area. HEC support in this regard will be beneficial, but institutions could also collaborate in devising and implementing policies in partnership, share resources including plagiarism detection mechanisms and help create and nurture an ethical ethos.

References

1. Marsh B. The plagiarism debate: History and context. In: *Plagiarism: Alchemy and Remedy in Higher Education*. Albany: Suny Press, 2007, pp 31-48.
2. Plagiarism at KU. Dawn, Oct 30, 2009.
3. Malik M. Plagiarism: accused UET teacher becomes accuser. Dawn, Oct 30, 2009.
4. Shah B. Battle against plagiarism. Dawn, Oct 27, 2009.
5. Cole AF. Plagiarism in Graduate Medical Education. *Family Med* 2007; 39: 436-8.
6. Sri Kantha S. Nobel prize winners for literature as palliative for scientific English. *Croat Med J* 2003; 44: 20-3.
7. Fuller JL, Killip DE. Do Dental Students Cheat? *J Dent Educ* 1979; 43: 666-9.
8. Bilic-Zulle L, Frkovic V, Turk T, Azman J, Petroveckii M. Prevalence of plagiarism among medical students. *Croat. Med J* 2005; 46: 126-31.
9. Baloch F. Cheating galore at schools turned into exam centre for their own students. *The News*, April 1, 2009. Available from URL: [Cheating galore at schools turned into exam centre for their own students](#).
10. Elzubeir MA, Rizk DE. Exploring perceptions and attitudes of senior medical students and interns on academic integrity. *Med Educ* 2003; 37: 589-96.
11. Teplitsky PE. Perceptions of Canadian dental faculty and students about appropriate penalties for academic dishonesty. *J Dent Educ* 2002;66: 485-95.
12. Sturcke J, Wainwright M. Disgraced Raj Persaud quits as consultants at leading hospital. *The Guardian*, October 24, 2008. Available from URL: <https://www.theguardian.com/lifeandstyle/2008/oct/24/raj-persaud-psychiatry-maudsley>.
13. Rimer S. When plagiarism's shadow falls on admired scholars. *New York Times*, November 24, 2004. Available from URL: <http://www.nytimes.com/2004/11/24/education/24harvard.html>.
14. HEC Plagiarism Policy and The Little Book of Plagiarism. (Online) Cited 2009 Aug 12. Available from <http://hec.gov.pk/english/services/faculty/Documents/Plagiarism/Little%20Book%20of%20Plagiarism.pdf>.
15. Syndicate lets guilty PU teachers off the hook. Dawn, April 3, 2007. (Online) 2007. Available from URL: <http://www.dawn.com/news/240473/syndicate-lets-guilty-pu-teachers-off-the-hook-plagiarism-confirmed>.
16. Ghumman K. HEC Stops Funding Punjab Varsity: Failure to Check Plagiarism. Dawn, April 4, 2007. (Online) 2009. Available from URL: <http://www.dawn.com/2007/04/04/top17.htm>.
17. HEC winds up coordinating unit for lack of funds. *The Daily Times*, Jan 5, 2009. (Online) 2009. Available from URL: http://www.dailytimes.com.pk/default.asp?page=2009\01\05\story_5-1-2009_pg7_20.

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Jamshed Akhtar, "Plagiarism: What authors need to know," *Journal of Surgery Pakistan, International*, vol. 13, no. 1 (2008): 1.
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Plagiarism: What Authors Need to Know

Jamshed Akhtar

Wikipedia, the free encyclopedia, describes Plagiarism as "the practice of claiming or implying original authorship of (or incorporating material from) someone else's written or creative work, in whole or in part, into one's own without adequate acknowledgement."¹ While on Higher Education Commission website with reference to Chambers dictionary a plagiarist is a kind of thief, "one who steals the thoughts or writings of others and gives them out as his [sic] own". When this is also used for gain in the University to gain credits for a module or modules – then an additional dimension of dishonesty is added.²

This is an important issue about which all authors ought to know and try not to indulge in it. Stating that one did not know about plagiarism is not accepted. The HEC website also shows details of how many university faculty members have been punished on account of being plagiarist. There was recent debate in press and electronic media regarding this professional misconduct and rightly so. If a faculty member himself is involved in these unethical practices how can he be trusted to inculcate a just and fair approach towards teaching and training of juniors.

There is a dire need of teaching authors as to how to avoid plagiarism. One should know how to cite references, phrase, and put quotation marks etc. It is therefore necessary for the authors to read the searched literature and then write discussion part based upon their own research and comparing what is reported in literature. This description should critically analyze similarities and differences. Plagiarism is easy to identify and many soft-wares are available to detect them. Paraphrasing is also a type of plagiarism and can also be picked up easily. At times the manuscript may get unnoticed and published. Someone then points out the plagiarism in that article. In this regard the editorial board is bound to ask for explanation and should also notify monitoring bodies like PMDC, HEC and concerned universities. Although the type of punishment to be given to such authors is not agreed upon but usually the editorial board blacklists such a person for some period of time and retracts such article.

We hope our contributors will not indulge into such unethical practices.

References:

1. www.wikipedia.org/wiki/Plagiarism What Is Plagiarism?
2. www.hec.gov.pk/QualityAssurance/Plagiarism.htm

Useful Links

- “The little book of plagiarism: What it is and how to avoid it,” *University of Stirling*, 4th edition, September 2014.
- Patrick Okonta, Theresa Rossouw, "Prevalence of scientific misconduct among a group of researchers in Nigeria," *Developing World Bioethics*, vol. 13, no. 3 (2013): 149-157. <http://onlinelibrary.wiley.com/doi/10.1111/j.1471-8847.2012.00339.x/full>.
- R. Grant Steen, Arturo Casadevall, Ferric C. Fang, "Why has the number of scientific retractions increased?," *PloS one*, vol. 8, no. 7 (2013): e68397. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0068397>.
- Daniele Fanelli, Rodrigo Costas, Vincent Larivière, "Misconduct policies, academic culture and career stage, not gender or pressures to publish, affect scientific integrity," *PLoS One*, vol. 10, no. 6 (2015): e0127556. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0127556>.
- “Scientific Misconduct,” *Wikipedia*. https://en.wikipedia.org/wiki/Scientific_misconduct.
- Robert A. Gross, “Statistics and the detection of scientific misconduct,” *Neurology*, vol. 87 no. 23 (2016): 2388. <http://www.neurology.org/content/87/23/2388.short>.

10: Ethics of Mental Healthcare

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Cases for Discussion

- **Case 1: Consent / Capacity**

A middle aged man is brought to the emergency by his brother, who informs the doctor that the patient took a handful of tranquilizers a couple of hours back. The brother feels that the patient has been severely depressed since he suffered a heavy financial loss in business 6 months ago. After an initial assessment, the doctor advises that a medico legal case be registered and admits the patient. The family refuses and takes the patient away.

How should the doctor deal with this situation? As an accident or attempted suicide?

- **Case 2: Confidentiality / Sharing of Information / Risk Assessment**

A 25 years old man has been forcefully brought by his parents to your clinic explaining that he tends to become aggressive, talks to himself and has stopped going out of the house. On examination, the young man shares his fears that their neighbor has been making plans to kill him. He has to act first and kill the neighbor. He has bought a big knife for the purpose.

How would you proceed?

- **Case 3: Property Disputes**

A 50 year old male brings his wife for consultation due to an eight years history of angry outbursts and fighting with him. The wife says that he is a womanizer, gives very little attention to and money for the family (four children), stays out late and wants to sell the house which is in her name.

Husband insists that she needs urgent admission because she is insane and does not understand that he needs the money to settle business losses.

How would you deal with this couple?

- **Case 4: Genetic Counseling / Confidentiality**

A young man gets engaged to his cousin whose brother suffers from 'schizophrenia,' and he seeks your advice about chances of mental illness in their offspring. They have been engaged since childhood. He asks you to not inform his fiancée of his consultation with you.

Are there any ethical issues for you in this case?

Some Ethical Issues Specifically Related to Mental Health Care

(Provided by Asma Humayun)

(1) Confidentiality / Consent

For general principles, please see section on Confidentiality in the handbook. These apply to most clinical scenarios in mental health care as well. But these need to be modified in cases of psychotic illness where patients lack insight and might refuse assessment or treatment. In these cases, mental health laws allow psychiatrist to over ride their autonomy; seek/share information with families, admit and even treat them without their consent.

Additionally, if there is risk of harm either to a patient (eg risk of suicide) or to others (eg paranoid delusions), the confidentiality of the patient is breached.

Reference: Sindh Mental Health Act, 2013 (Chapter II sections 9-12)

<http://www.pas.gov.pk/uploads/acts/Sindh%20Act%20No.L%20of%202013.pdf>

Please note:

Mental Disorder is defined as:

“Mental disorder” means a mentally ill person who is in need of treatment by reason of any disorder of the mind other than mental impairment and severe personality disorder be construed accordingly.

(Ref: SMHA 2013, Page 2)

(2) Attempted Self harm/Suicide

According to Sindh Mental Health Act, 2013 (Chapter VII Page 26) a person who attempts suicide should be offered a psychiatric assessment and treatment, where needed. This is in contrast to the criminal law of Pakistan where suicide/attempted suicide is considered a crime that needs to be reported to the police.

3) Specialized Treatments: Specific ethical issues are relevant to some invasive

treatments/procedures in psychiatric practice. These include electro-convulsive therapy, Depot Anti-psychotic injections, Psychosurgery (not performed now) etc.

1. All electro-convulsive treatments shall preferably be administered under general anesthesia.
2. All electro-convulsive treatments shall be advised by a psychiatrist, incharge of the patient, recording the reasons for such advice and stating the reasons as to why the alternative available methods of treatment are not appropriate.
3. Administration of long acting anti-psychotic depot injections shall only be carried out upon the advice of a psychiatrist for a period as specified in the prescription and such cases shall be reviewed periodically.
4. No person shall advise and carry out psychosurgery or make any decision to carry out psychosurgery, except in cases where it is decided to be necessary and appropriate in a meeting in this regard, attended by a neurosurgeon, a neuro-physician, a physician, two approved psychiatrists and a clinical psychologist. (Chapter XI. MISC 56, 2, 3, 4 & 5 of SMHA 2013).

Reference: Sindh Mental Health Act 2013, Chapter XI, Page 26 – link below:
<http://www.pas.gov.pk/uploads/acts/Sindh%20Act%20No.L%20of%202013.pdf>.

4. Torture

World Medical Association in its declaration of Tokyo, 1975, says “the deliberate, systematic or wanton infliction of physical or mental suffering by one or more persons acting alone or on the orders of any authority, to force another person to yield information, to make a confession, or for any other reason”.

Pakistan Medical Association has condemned torture/flogging and advised members to avoid participation (Resolution 8th September 1983).

For further details, please refer to Integrating Behavioural Sciences in Healthcare by Humayun & Herbert, Chapter 4.6, page 209-212.

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Asma Humayun, Michael Herbert, “The Burden of Mental Health Problems,” chp. 6.1, *Integrating Behavioural Sciences in Healthcare*, Higher Education Commission, Pakistan (2010).

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INTEGRATING BEHAVIOURAL SCIENCES IN HEALTHCARE

The Burden of Mental Health Problems

Asma Humayun, Michael Herbert

For a long time, healthcare focused mainly on illnesses that threatened life. The health burden was calculated by 'mortality'. Diseases associated with greater mortality e.g., heart diseases and cancer received more attention. There were many conditions which were ignored because, despite causing severe disability and suffering, they were not considered life threatening. Clearly there was need to measure the impact of diseases in a broader context.

The 'Global Burden of Disease' (GBD) calculates the burden of disease in each country by combining the mortality (years of life lost through premature mortality, YLL) and morbidity (years lived with disability, YLD) associated with each disease (Murray & Lopez, 1996). The global disease burden is expressed in terms of 'Disability Adjusted Life Years' (DALYs). This enables us to quantify the impact of a disease not only in terms of the number of deaths, but also by accounting for premature death and disability. With this shift in method, many of the major causes of mortality (e.g., communicable diseases) remained prominent; however the burden of many disabling but non-fatal disorders was now recognised. It was at this point that the burden of (previously ignored but) highly prevalent and disabling mental disorders was recognised.

Box 1 lists 10 leading causes of health burden (Murray & Lopez, 1996). Depression, a common mental illness is currently reported to be the fourth leading cause of disease burden. But it is likely to become the second largest cause of disability in the world after heart diseases by the year 2020.

10 leading causes of health burden		
Rank	Cause	%DALYs lost
1.	Lower respiratory diseases	7.3
2.	Diarrhoeal diseases	6.5
3.	Perinatal conditions	6.1
4.	Major Depressive Disorders	4.2
5.	Ischaemic Heart Disease	4.0
6.	HIV	3.4
7.	Cerebrovascular disease	3.2
8.	Road traffic accidents	3.0
9.	Malaria	3.0
10.	Tuberculosis	3.0

Box 1: 10 leading causes of health burden (Murray & Lopez, 1996)

It is important to note that even the other causes e.g., coronary heart disease, HIV and accidents have a significant contribution of psychosocial factors in their aetiology and prevention (see Section 4). In view

of the undeniably significant role of mental health, the WHO proposed a slogan that there can be “no health without mental health” (2005).

Mathers & Loncar (2006) estimated that mental disorders accounted for 14% of the total burden of disease in 2005 and 28% of the non-communicable diseases (Box 2). This is not just likely to increase by the year 2020 but much of this increase is likely to come from low income countries. It is worthwhile to note that this burden is nearly equal to cardiovascular disorders and more than the burden of cancer and many other disorders (WHO, 2001). Some of these conditions are further discussed in Chapter 6.2.2.

Burden of neuropsychiatric conditions	
Depressive disorder	10%
Substance-use and alcohol use-disorders	4%
Bipolar affective disorder	2%
Schizophrenia	2%
Dementia	2%
Epilepsy	1%
Other mental disorders	3%
Other neuropsychiatric disorders	3%
Other neurological disorders	2%

Box 2: Contribution of neuropsychiatric conditions towards the burden of non-communicable diseases (Mathers & Loncar, 2006)

6.1.1 Why is the Burden so Huge?

In part, the excess disability due to mental disorders is a result of their early age of onset (WHO, 2000). But Kohn, et al., (2004) reported that the magnitude of this burden also results from the fact that only a minority of individuals with these disorders ever receive treatment, resulting in a huge 'treatment gap'. The treatment gap represents the absolute difference between the true prevalence of a disorder and the treated proportion of individuals affected by the disorder. Alternatively, the treatment gap may be expressed as the percentage of individuals who require care but do not receive treatment. According to the WHO report (2000), the treatment gap for depression is 45.4% (European Region), 56.9% (the Americas) and 67% (Africa).

They summarised numerous reasons for existing treatment gaps for mental disorders (also see Chapters 3.3 & 3.4). These include:

1. Not acknowledging the problem
2. Perceiving that treatment is not effective
3. Believing that the problem will go away by itself
4. Desiring to deal with the problem without outside help
5. Lacking knowledge about mental disorders
6. Facing stigma as a major barrier
7. Lack of availability of services
8. Lack of accessibility to services including financial considerations

6.1.2 Prevalence of Mental Disorders in Pakistan

There is a general lack of epidemiological research on mental disorders in Pakistan. But a high prevalence of common mental disorders like depressive and anxiety disorders has been suggested by some studies in different parts of the country. Mirza & Jenkins (2004) suggested the overall prevalence of anxiety and depressive disorders to be 34% in the community (range 29-66% for women and 10-33% for men). In view of considerable methodological limitations, these findings cannot be extrapolated to the whole of

Pakistan and stronger evidence is needed. These studies also indicate that socioeconomic adversity and relationship problems were major risk factors for anxiety and depressive disorders in Pakistan, whereas a supportive family and friends may protect against the development of these disorders.

The prevalence of mental retardation in children was studied by Durkin, et al., (1998) in a survey of 2 to 9 year olds. The prevalence of mental retardation was 1.9% for serious retardation and 6.5% for mild retardation. Lack of maternal education, perinatal difficulties, neonatal infections, postnatal brain infections and injury and malnourishment were associated with it. Yaqoob, et al., (1995) assessed urban children in four different socioeconomic groups. The incidence of severe mental retardation per 1000 live births was 22 (peri-urban slums), 9 (urban slums), 7 (village) and 4 (upper middle class). Down syndrome was the most common cause of severe mental retardation (36%). Bashir, et al., (2002) found that the prevalence of mild mental retardation was higher in Pakistan than in developed countries. They also found the rates to be significantly higher for poor children, thus suggesting an association with socioeconomic conditions.

6.1.3 Costs of Mental Health Problems

Mental health problems cause enormous burdens. We now examine the nature of this burden on individuals and society. This can be related to:

1. Disability
2. Mortality
3. Economic impact
4. Burden on families

6.1.3.1 Disability

Mental disorders are an important cause of long-term disability and dependency. According to the WHO, neuropsychiatric conditions cause 31.7% of all years lived-with-disability (YLD) (Mathers & Loncar, 2006). These conditions are listed in Box 3:

Major (neuropsychiatric) contributors to YLD

1. Depression 11.8%
2. Substance-use disorder 3.3%
3. Schizophrenia 2.8%
4. Bipolar disorder 2.4%
5. Dementia 1.6%

Box 3: Major (neuropsychiatric) contributors to YLD (Mathers & Loncar, 2006)

1. Physical Disability

Depression contributes to the onset and progression of both physical and social disability:

Mental disorders are known to worsen physical ability e.g., in relation to activities of daily living (Bruce, et al., 1994). These also influence physical health adversely. The interaction between mental and physical health is complex (see Section 4).

2. Social Disability

Janca, et al., (1996) reported that in mental disorders such as schizophrenia, social disability can affect various areas:

- Self-care
This refers to personal hygiene, dressing and feeding.
- Occupational performance
This refers to expected functioning in paid activities, studying, homemaking.

- Functioning in relation to family and household members
This refers to expected interactions with spouses, parents, children or other relatives.
- Functioning in a broader social context
This refers to socially appropriate interaction with community members, and participation in leisure and other social activities.

We have discussed how stigma is likely to affect a person's identity and leads to a damaged sense of self through social rejection, discrimination and social isolation (see Chapter 3.5.2). This is particularly true for the 'mentally ill' who face adverse social consequences. Desjarlais, et al., (1995) highlighted the use of pejorative language, barriers to employment, restricted access to social services, fewer chances for marriage, increased mistreatment and institutionalisation.

6.1.3.2 Mortality

Mental disorders contribute to mortality as persons with mental disorders have an increased risk of premature death. According to the WHO, neuropsychiatric disorders account for 1_2 million deaths every year (Mathers & Loncar, 2006). In addition, about a million people across the world die by suicide every year (Bertolote & Fleischmann, 2002). Alarming, 86% of these are in low-income and middle-income countries, and more than half of these are aged between 15 and 44 years. Even these figures might be underestimated, since official statistics in developing countries are not reliable. Cavanagh, et al., (2003) showed that mental disorders (e.g., depression) were responsible for 91% of suicides. Khan, et al., (2008) confirmed that 96% of individuals who died by suicide in Karachi, suffered from a mental disorder.

6.1.3.3 Economic Burden

Mental disorders have wide ranging economic impacts on the individual and society (Desjarlais, et al., 1995). These include direct and indirect costs. In depressive disorders, the components of the direct costs include medical consultations, hospitalisation, and medication (whether these are borne by the state or by the individuals and families). Indirect costs are the result of being unable to work, claiming incapacity benefits (in welfare states), or if a family member takes time out of work to care for the ill. This cause of lost productivity is particularly common in developing countries where health and support services are seriously deficient. Chisholm, et al., (2000) identified evidence on service use and costs in two districts of India and Pakistan. Combining health care and patient/family costs, the economic impact of depression and anxiety in the Bangalore was Indian Rupees 700 per month, but in Rawalpindi it was more than Pakistani Rupees 3000 per month. This was equivalent to between 7 and 14 days of wages of an agricultural worker in India, and approximately 20 days work in Pakistan.

Similarly the total cost of managing depression in adults in the UK has been estimated to be very high (Thomas & Morris, 2003). They reported that the contribution of the cost of antidepressant medication is only a minor proportion of the overall cost but the indirect burden associated with depression is substantial.

6.1.3.4 Burden on Families

The intangible elements of pain and suffering of people with depressive disorders and their families and the effects on quality of life cannot be quantified in monetary terms. The magnitude of unpaid caring is enormous (Salleh, 1994). They found that 41% of families caring for a mentally ill member in Malaysia experienced emotional burden.

Various sources of stress include:

- Emotional reactions to the patient's illness, such as guilt, a feeling of loss and fear about the future
- The stress of coping with disturbed behaviour
- Disruption of household routine
- Problems of coping with social withdrawal or awkward interpersonal behaviour
- Curtailment of social activities.

Key points

Mental disorders:

- ✓ are very common
- ✓ are prevalent in all countries / all cultures
- ✓ cause significant disability

References

1. Bashir, A., Yaqoob, M., Ferngren, H., Gustavson, K-H., Rydelius, P-A., Ansari, T., et al. (2002). Prevalence and associated impairments of mild mental retardation in six- to ten-year old children in Pakistan: A prospective study. *Acta Paediatrica*, 91, 833-837.
2. Bertolote, J. M., & Fleischmann, A. (2002). A global perspective on the epidemiology of suicide. *Suicidolog*, 7, 6-8.
3. Bruce, M. L., Seeman, T. E., Merrill, S. S., & Blazer, D. G. (1994). The impact of depressive symptomatology on physical disability: MacArthur Studies of Successful Aging. *Am. J Public Health*, 84, 1796-1799.
4. Cavanagh, J. T., Carson, A. J., Sharpe, M., & Lawrie, S. M. (2003). Psychological autopsy studies of suicide: A systematic review. *Psychol med*, 33, 385-405.
5. Chisholm, D., Sekar, K., Kishore Kumar, K., Saeed, K., James, S., Mubbashar, M., et al. (2000). Integration of mental health care into primary care: Demonstration cost-outcome study in India and Pakistan. *Br J Psych*, 176, 581-588.
6. Desjarlais, R., Eisenberg, L., Good, B., & Kleinman, A. (1995). *World mental health. Problems and priorities in low income countries*. Oxford: Oxford University Press.
7. Durkin, M. S., & Hasan, K. Z. (1998). Prevalence and correlates of mental retardation among children in Karachi, Pakistan. *Am J Epidemiol*, 147, 281-288.
8. Janca, A., Kastrup, M., Katschnig, H., Lopez Ibor, J. J., Mezzich, J. E., & Sartorius, N. (1996). The World Health Organization Short Disability Assessment Schedule (WHO DAS-S): A tool for the assessment of difficulties in selected areas of functioning of patients with mental disorders. *Soc Psychiatry and psychiatric epidemiol*, 31, 349-354.
9. Khan, M. M., Mahmud, S., Karim, S. M., Zaman, M., & Prince, M. (2008). Case-control study of suicide in Karachi. *Br J Psychiatry*, 193, 402-405.
10. Kohn, R., Saxena, S., Levav, I., & Saraceno, B. (2004). The treatment gap in mental health care. *Bull World Health Organ*, 82, 858-866.
11. Mathers, C. D., & Loncar, D. (2006). Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med*, 3 (11), e442.
12. Mirza, I., & Jenkins, R. (2004). Risk factors, prevalence, and treatment of anxiety and depressive disorders in Pakistan: systematic review. *Br Med J*, 328, 794-799.
13. Murray, C. L., & Lopez, A. D. (Eds.). (1996). *The global burden of disease: A comprehensive assessment of mortality and disability from diseases, injuries and risk factors in 1990 and projected to 2020*. Cambridge, MA: Harvard School of Public Health on behalf of WHO & World Bank.
14. Salleh, M. R. (1994). The burden of care of schizophrenia in Malay families. *Acta Psychiatrica Scandinavica*, 89, 180-185.
15. Thomas, C. M., & Morris, S. (2003). Cost of depression among adults in England in 2000. *Br J Psychiatry*, 183, 514-519.

16. WHO International Consortium in Psychiatric Epidemiology. (2000). Cross-national comparisons of the prevalences and correlates of mental disorders. *Bull World Health Organ*, 78, 413-425.
17. WHO. (2005). *Mental health: Facing the challenges, building solutions*. Report from the WHO European Ministerial Conference. Copenhagen, Denmark: World Health Organization.
18. WHO. (2001). *Mental health: New understanding, new hope*. Geneva: World Health Organisation.
19. Yaqoob, M., Bashir, A., Tareen, K., Gustavson, K.-H., Nazir, R., Jalil, F., et al. (1995). Severe mental retardation in 2 to 24-monthold children in Lahore, Pakistan: A prospective cohort study. *Acta Paediatrica*, 84, 267-272.

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INTEGRATING BEHAVIOURAL SCIENCES IN HEALTHCARE

Mental Health Legislation

Asma Humayun, Michael Herbert

People with mental health problems are vulnerable in many ways. Mental illnesses affect the way people think, feel and behave. These illnesses may affect their capacity and performance in some way even if it is for a limited time only. Sometimes, but not always, their ability to make decisions is also affected. Then there are certain conditions where insight is affected (see Chapter 6.2.2.2) and they may not always seek and accept treatment. We have also seen that people with mental illness face stigma, discrimination and marginalisation in all societies. As a result, they are usually offered a service of inferior quality which is insensitive to their needs. Such marginalisation and discrimination increases the risk of violation of their civil and human rights. Infrequently, they may pose a risk to themselves or to others due to impairment in their judgement and associated behavioural disturbances. Hence there is a need to protect them, their family members, neighbours and society at large.

6.6.1 Why do we Need Legislation for Mental Health Care?

Contrary to the common belief that we need a law for mentally ill people to lock them up and protect society, we actually need a law to protect those who are at the greatest risk - mentally ill people themselves. Violations of the human rights of the mentally ill have been reported from most countries (WHO, 2005). The UN established basic 'Principles for the Protection of Persons with Mental Illness and the Improvement of Mental Health Care' (1991). These principles provide a framework for the development of mental health legislation all over the world. These principles recognise that every person with a mental disorder has a right to live and work, as far as possible, in the community. They also establish that people with mental illnesses need to receive appropriate healthcare and need protection of their rights when care is either offered voluntarily or enforced compulsorily. A related component is the principle of least restrictive alternative. This means that all individuals are entitled to be treated in the community with as few restrictions as possible (except in circumstances such as risk of potential harm to self or others). So that it is only in exceptional circumstances that individuals are admitted to care against their wishes and subjected to forcible treatment. It is during such forced or involuntary admissions, that the risk of violation of their rights increases.

The WHO (2005) reports "Countries continue to lock up patients in 'caged beds' for hours, days, weeks, or sometimes even months or years. A couple of patients have lived in these devices nearly 24 hours a day for at least the last 15 years." Levav & Gonzalez Uzcategui (2000) showed that such abuses were more common in the public sector compared to private hospitals where mental health workers had a greater awareness of patient rights.

These principles also address other critical mental health issues such as access to care, provision of high quality care, full integration of people with mental illness into the community, protection of their civil rights and promotion of mental health in different sectors of society. They emphasise protecting their rights to confidentiality, informed consent and competency etc. Outside the health sector, issues related to housing, employment, civil matters and their involvement with the criminal justice system are also included.

6.6.2 Basic Principles of Mental Health Legislation

Based on the above principles, the WHO developed the Mental Health Care Law: Ten Basic Principles as a guide to assist countries in developing mental health law (1996). These are shown in Box 1.

Mental Health Care Law: Ten Basic Principles

1. Promotion of mental health and prevention of mental disorders
2. Access to basic mental health care
3. Mental health assessments in accordance with internationally accepted principles
4. Provision of least restrictive type of mental health care
5. Self-determination
6. Right to be assisted in the exercise of self-determination
7. Availability of review procedure
8. Automatic periodic review mechanism
9. Qualified decision-maker [refers to a trained specialist who can override patient's right (under the legislation) to make a decision about management]
10. Respect for the rule of law

Box 1: Mental Health Care Law: Ten Basic Principles (WHO, 1996)

6.6.3 Mental Health Ordinance 2001

Mental health legislation varies greatly between different countries. Some developing countries still do not have relevant legislation and others continue to rely on outdated legislation. Until 2001, Pakistan was also one of these countries where the legislation was outdated in the form of the Lunacy Act 1912 (Government of Pakistan). Keeping in view the basic principles for mental health care outlined above, new legislation was enacted as the 'Mental Health Ordinance' (MHO) (2001). This was an important development. The care of people with mental disorders has evolved greatly during the last century. This is partly because of advances in medical science and partly because of a social movement to restore humane care to protect the rights of the mentally ill. A primitive law like the 'lunacy act 1912' continued to reinforce a highly stigmatised view of mental disorders and offered no framework for implementing contemporary guidelines for treatment and care. The new legislation addressed various aspects of care in a scientific and humane manner. Gilani, et al., (2005) pointed out that even replacing outdated

terminology like 'lunatic' and 'asylum' with 'mentally disordered' and 'mental health facility' respectively reflects an empathic and progressive attitude of society towards the mentally ill.

The salient features of the mental health ordinance are as follows:

6.6.3.1 Access to Mental Health Care

We have seen how huge the burden caused by mental illnesses is. We also know that the resources to deal with the magnitude of the problem are scarce. As a result, many people suffering from even common mental illnesses never receive treatment and care. We learned that the possible solution is to strengthen the care for mental health via primary care. The MHO emphasises that appropriate services must be developed: Community based mental health services shall be set up for providing services (MHO, chapter III, section 7). People must have access to care closest to where they live. And for those who are severely unwell, facilities must be available to refer for specialist care. Similarly, the law reinforces the need for availability of drugs required for treating mental illnesses.

Another glaring example of the lack of access to mental health care is for people who attempt to harm or kill themselves. We know that the majority who do so are mentally unwell and need to be assessed. Without the MHO, this is considered a 'crime' and has to be reported to the police.

The ordinance clearly states that such persons must be assessed by a psychiatrist to exclude mental health issues (MHO, chapter VII, section 49).

6.6.3.2 Establish National Standards and Guidelines for Treatment

The standards of care vary greatly between different centres within the country. Most guidelines for treatment are developed in the west which might not always be applicable in developing countries. Therefore, there is lack of consensus on effective and evidence based management plans, even for common mental disorders. For example, in our experience, most doctors working in A&E continue to struggle and experiment with patients presenting in dissociative states. These are stress related disorders and were previously grouped under the term 'Hysteria'. It is a common practice to make such unresponsive patients smell 'ammonia' to 'wake them up'. Then there are specialised treatments like ECT (electroconvulsive therapy), the application of which needs to be standardised and monitored. It is hoped that when the law enforces standard treatment guidelines, appropriate facilities and resources will be made available at all mental health facilities.

6.6.3.3 Establish Independent Mechanisms for Monitoring Care

The MHO clearly defined informed consent and makes it the basis for care, as much as possible. It monitors, through rigorous and ongoing procedures, the application of involuntary admissions and treatments. Previously people were often forced to remain at mental hospitals for months or years without any right to challenge their detention. Now involuntary admissions are limited to specific periods during which the person must be assessed by a specialist at the earliest (MHO, chapter III, section 9-10). Similarly, people were ill treated within mental hospitals where they were restrained by metal shackles, kept in seclusion for lengthy periods, kept in poor living conditions and subjected to other inhumane treatments. The ordinance recommends checking procedures to ensure scientific and humane care at all mental health facilities and advises punishments for staff involved in any ill treatment.

6.6.3.4 Promote Positive Mental Health and Prevent Mental Illnesses

We discussed some strategies for the promotion of mental health and prevention of mental illnesses in Chapters 6.3 & 6.4. We also learned that these extend beyond the domain of health professionals and that other agencies need to be involved in implementing policy and plans for these interventions. The law directs all stakeholders to take appropriate measures.

6.6.3.5 Protect the Rights of People with Mental Disorders

Emphasis is placed on the protection of human rights of persons who are mentally disordered (MHO, chapter VII). It grants patients their basic right to understand their options and be part of making decisions about their care. It also emphasises their right to confidentiality. It strictly prohibits ill treatment or exploitation of a mentally disordered person in any way. It prohibits anyone from making statements which discredit someone as mentally disordered.

“Any person who carries out any form of inhumane treatment on a mentally disordered person which includes: trepanning, branding, scalding, beating, chaining to a tree subjecting a child to the cultural practice of rendering him mentally retarded by inducing microcephaly or subjecting any person to physical, emotional or sexual abuse, shall be guilty of an offence, punishable with rigorous imprisonment which may extend to five years or with fine extending up to Rs 50,000 or both”. (MHO, chapter VIII, section 5)

Inducing microcephaly is part of a gruesome practice in children, who are then called the 'Shah Dola Rats' at the shrine of Shah Dola in Gujrat. Traditionally, infertile women pray there and commit to devote their first born (always believed to be microcephalic) to serve the shrine. Human Rights groups believe the rat children of Shah Dola are being deliberately deformed by having their heads fitted with iron caps which restrict their growth and also cause severe brain damage. They then exploit them as beggars. These individuals are severely handicapped both mentally and physically, but are considered close to God and, thus, make lucrative beggars. It is also reported that these rat-children are victims of persistent sexual abuse as their severe mental disabilities make them silent (Galpin, 1998).

6.6.3.6 Protect Civil Rights

People are often deprived of their civil rights, such as the right to vote, or the right to marry and have children. They experience discrimination in all areas of life including employment, education and the right to housing. It is not uncommon for people with mental disorders to be victimised and deprived of their property and estates. The ordinance directs the courts to ensure that their interest is protected (MHO, chapter V).

6.6.3.7 Protect the Rights of Mentally Ill Offenders

In some countries, people with mental disorders are locked up in prisons because of a lack of mental health services or diagnosis and treatment of their condition. The disorders of these 'prisoners' therefore continue to go unnoticed, undiagnosed and untreated. The WHO recommends that people with mental disorders be diverted away from the criminal justice system and towards mental health services. The ordinance orders regular check up for prisoners who might have mental health problems (MHO, chapter IX).

Although this legislation is a step in the right direction, its implementation and revision is a dynamic process which needs to evolve over a longer period of time. Any concerns, apprehensions or fears relating to the legislation, must be addressed at professional forums. Public education and awareness campaigns to highlight the substantial provisions of the legislation, more particularly the rationale and philosophy underlying these changes are required. Media strategies can be most useful in raising awareness and advocacy. Mental health advocacy groups can also play a major role. It is important to lobby key members of the government, ministries, legislature and political parties. Key informants and stakeholders need to be interviewed to identify the main barriers impeding implementation. If there is shortage of mental health manpower or resistance from professional groups, training programs should be arranged for key professional groups. If there is insufficient funding to develop the mechanisms needed to implement the law (e.g. advocacy, awareness raising, training, visiting boards, complaints procedures), partnerships with key stakeholders must be established.

Key points

The Mental Health Ordinance 2001:

- ✓ Promotes access to mental health care
- ✓ Protects the rights of people with mental disorders
- ✓ Promotes positive mental health and the prevention of mental illnesses

References for Mental Health Section

1. Galpin, R. (1998, June 29). The rat children of Pakistan. Retrieved from London: BBC News: http://news.bbc.co.uk/1/hi/world/south_asia/122670.stm
2. Gilani, A. I., Gilani, U. I., Kasi, P. M., & Khan, M. M. (2005). Psychiatric health laws in Pakistan: From lunacy to mental health. *PLoS Med*, 2 (11), e317.
3. Government of Pakistan. (1912). Lunacy Act.
4. Government of Pakistan. (2001). Mental Health Ordinance. Law, Justice and Human Rights Division. Islamabad: Ordinance No VIII of 2001, The Gazette of Pakistan.
5. Levav, I., & Gonzalez Uzcatogui, R. (2000). Rights of persons with mental illness in Central America. *Acta Psychiatr Scand*, 101, 83-86.
6. United Nations. (1991). Principles for the protection of persons with mental illness and the improvement of mental health care (MI Principles). Retrieved from UN General Assembly Resolution 46/119: <http://www.unhcr.ch/html/menu3/b/68.htm>.
7. WHO. (1996). Mental Health Care: Ten Basic Principles. Retrieved from World Health Organisation: http://whqlibdoc.who.int/hq/1996/WHO_MNH_MND_96.9.pdf.
8. WHO. (2005). Resource book on mental health, human rights and legislation. Geneva: World Health Organisation.

Useful Links

- Sindh Mental Health Ordinance 2001. *Sindh Govt. Press*, Karachi, Pakistan.
<http://pamh.org.pk/wp-content/uploads/2015/11/Mental-Health-Ordinance-2001.pdf>.
 - Sindh Mental Health Act 2013. *Sindh Govt. Press*, Karachi, Pakistan.
<http://www.pas.gov.pk/uploads/acts/Sindh%20Act%20No.L%20of%202013.pdf>.
 - Melvyn Freeman, Soumitra Pathare, “*WHO Resource Book on Mental Health, Human Rights and Legislation*, World Health Organization (2005).
http://www.who.int/mental_health/policy/legislation/en/.
 - Robertson, Michael, Garry Walter, "Overview of psychiatric ethics I: Professional ethics and psychiatry," *Australasian Psychiatry* 15, no. 3 (2007): 201-206.
<http://www.heti.nsw.gov.au/Global/HETI-Resources/psychiatry/An%20Overview%20of%20Psychiatric%20Ethics.pdf>.
 - Marguerite Reid Schneider, "Clinical and social contexts of ethical issues in mental health care." *AMA Journal of Ethics* 18, no. 6 (2016): 567.
<http://journalofethics.ama-assn.org/2016/06/fred1-1606.html>.
 - Stephen Feldman, “Legal and Ethical Issues for Mental Health Professionals, Volume II: Dual Relationships, Boundaries, Standards of Care and Termination. (2013).
<https://www.youtube.com/watch?v=MP8vydACbg4>.
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