

Current Ethical Challenges in Obstetric and Gynecologic Practice, Research and Education





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Foreword

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For the FIGO Committee on Ethical and Professional
Aspects of Human Reproduction and Women's Health



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Foreword

Professionalism and ethics are essential components of excellent patient care, research, and education and, therefore, of utmost importance to International Federation of Gynecology and Obstetrics (FIGO). FIGO's commitment to professionalism and ethics is represented in the title of this volume: *Current Ethical Challenges in Obstetric and Gynecologic Practice, Research, and Education*. Members of our FIGO Committee on Ethical and Professional Aspects of Reproductive Medicine and Women's Health created original work for the chapters of this book.

The first three chapters address ethical challenges in the clinical setting: The Fetus as a Patient; Ethical Issues in Women with HIV; and Consent in Emergency Obstetrics. The next chapter addresses Ethical and Legal Concerns in Uterine Transplantation. Four chapters address an often neglected set of ethical challenges, the Intersection of Health Policy and Clinical Practice: Sexual and Reproductive Health Services; Conscientious Objection and the Duty to Refer; Conflicts of Interest; and Criminalization of Criminal Errors. Each of these chapters provides ethically sound and clinically applicable guidance to the ethical challenges that are addressed.

The FIGO has a longstanding commitment to education. This volume makes a comprehensive contribution with a section on education about ethical challenges in obstetrics and gynecology. This section begins with a concise and accessible introduction to ethical reasoning. There follow case studies that apply this framework to a wide range of cases.

The FIGO proudly presents *Current Ethical Challenges in Obstetric and Gynecologic Practice, Research, and Education*.

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Preface

The International Federation of Gynecology and Obstetrics (FIGO) has supported a Committee on Ethical Aspects of Reproductive Medicine and Women's Health for many years because FIGO realizes that ethics is an essential dimension of clinical practice, research, the intersection of health policy and clinical practice, and education. The Committee's main task is to prepare—and keep current—statements on ethical aspects of reproductive medicine and women's health, emphasizing the professional responsibilities of obstetricians and gynecologists to patients, research subjects, health policy makers, educators, and societies around the world.

With this book, the committee expands the scope of its service to these constituencies, especially FIGO members. The book has four sections. The first, clinical practice, includes three chapters. One addresses the ethical concept of the fetus as a patient and its myriad clinical dimensions and implications. The two especially challenging clinical, ethical topics are addressed in depth, the care of women with HIV infection and consent in obstetric emergencies. The second section addresses an emerging and controversial topic in research ethics, uterine transplantation. The third section addresses the important—and sometimes neglected—intersection between health policy and clinical practice in the domains of sexual and reproductive health services, conscientious objection, conflict of interest, and criminalization of medical errors. The fourth section addresses bioethics education in obstetrics and gynecology. In 2012, the committee produced a clinically comprehensive, ethically reasoned, and case-based approach to ethics in obstetrics and gynecology, under the very capable leadership of then-chair of the committee, Bernard M Dickens. This pedagogical aid will enable FIGO members and other readers to design and implement ethics curricula for medical students, residents, and practicing obstetrician-gynecologists.

Frank A Chervenak
Laurence B McCullough



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We express our appreciation for the professionalism and hard work of the members of the FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health.

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Contents

SECTION 1: CLINICAL ISSUES

- 1. The Fetus as a Patient.....3**
Frank A Chervenak, Laurence B McCullough
 - Ethical Concept of the Fetus as a Patient 3
 - Implications of the Ethical Concept of the Fetus as a Patient 6
 - Innovation and Research 8
- 2. Ethical Issues in Women with HIV10**
Motshedisi Sebitloane
 - Reproductive Rights of HIV-infected Women 12
 - HIV in Pregnancy 13
 - Ethical Considerations in HIV-infected Women Seeking Assisted Reproduction 15
- 3. Consent in Emergency Obstetrics19**
Michael S Marsh
 - Informed Consent 19
 - Time Available for Consent in an Emergency 21
 - Evidence for the Effectiveness of Consent 21
 - Improving or Adjusting the Consent Process 24
 - Deferred Consent 24
 - Other Techniques to Improve the Consent Process 24
 - A Suggested Approach to Consent in Extremis 25
 - Practice Points 25

SECTION 2: RESEARCH

- 4. Ethical and Legal Concerns in Uterine Transplantation33**
Bernard M Dickens
 - Uterus Transplantation 35
 - Live-related Donation 36
 - Live-unrelated Donation 39
 - Deceased (Cadaveric) Donation 42
 - Uterus Recipients 45
 - Legal Concerns Requiring Ethical Responses 47

SECTION 3: THE INTERSECTION OF HEALTH POLICY AND CLINICAL PRACTICE

- 5. Main Challenges in the Professional Practice of Obstetricians and Gynecologists in Sexual and Reproductive Health Services.....55**
Leonel Briozzo
 - Sexual and Reproductive Rights 55

- Professional Values and Medical Professionalism 56
 - Bioethical Principles and Professional Practice 57
 - Main Challenges in Obstetricians' and Gynecologists' Practice of Sexual and Reproductive Rights 57
 - Perspectives for Professional Actions in the Sexual and Reproductive Health Services 58
 - Commitment to Patients: The Key for Medical Professionalism in Obstetrics and Gynecology 60
- 6. Conscientious Objection and the Duty to Refer62**
Bernard M Dickens
- Freedom of Conscience 63
 - Scope of Objection 64
 - Healthcare Institutions 66
 - Duty to Refer 68
 - Voluntary Surrender of Rights 70
 - Medical Monopoly 72
 - Conscientious Commitment 73
- 7. Current Ethical Challenges Facing the Obstetrician-Gynecologist: Conflict of Interest.....80**
Ralph W Hale
- Definition 81
 - Conflict of Interest Areas 83
 - Managing Conflict of Interest 86
- 8. Criminalization of Medical Errors89**
Sanjay Gupte
- Increasing Trend toward Criminalization of Negligence 89
 - Relevant Concepts 90
 - Assessing Criminalization of Negligence 92
 - One Remedy 95

SECTION 4: ETHICS EDUCATION IN OBSTETRICS AND GYNECOLOGY

- 9. FIGO Introduction to Principles and Practice of Bioethics 101**
Bernard M Dickens
- Background of Bioethics 102
 - Ethics Principles 103
 - Levels of Analysis 105
 - Clinical Case Analysis 107
- 10. Case Studies in Women's Health (Committee on Ethical Aspects of Human Reproduction and Women's Health) 109**
Bernard M Dickens
- Adolescent Sex and Confidentiality 110
 - Adolescents and Family Planning 112

- Anencephaly and Late-term Abortion 113
- Antenatal Care 115
- Bioethics and Faith-based Organizations 117
- Cesarean Section on Request 118
- Choice of Home Birth 120
- Clinical Research 121
- Conflict of Interest 123
- Cost Containment 124
- Egg Donation 126
- Female Genital Cutting/Mutilation 128
- Hepatitis B Vaccination 129
- Human Papillomavirus Vaccination 131
- Hysterectomy 133
- Illiterate Patients' Informed Consent 134
- Involuntary Female Sterilization 136
- Multiple Pregnancy 137
- Obstetric Fistula 139
- Refusal of Cesarean Section 141
- Refusal of Treatment 142
- Reinfibulation 144
- Social Sex Selection 145
- Surrogacy 147
- Task Shifting and Maternal Mortality 149
- Termination of Adolescent Pregnancy 150

Appendix 157

Index 159

Section 1

Clinical Issues

CHAPTERS

The Fetus as a Patient

Frank A Chervenak, Laurence B McCullough

Ethical Issues in Women with HIV

Motshedisi Sebitloane

Consent in Emergency Obstetrics

Michael S Marsh



The Fetus as a Patient

Frank A Chervenak, Laurence B McCullough

INTRODUCTION

The discourse of the “fetus as a patient” dates back at least four decades.^{1,2} The phrase was used to mean that interventions for fetal benefit had become clinical reality, e.g. intra-uterine transfusion for the clinical management Rh isoimmunization. This procedure is lifesaving, which is of obvious fetal benefit. Obstetric ultrasound and fetoscopy—even though clinically primitive by today’s standards—allowed diagnostic imaging of the fetus for first time. As a result of these diagnostic and therapeutic advances, the discourse of the fetus as a patient gained momentum. In the mid-1980s, the authors were the first to set out the ethical concept of the fetus as a patient, which had only been implicit in the discourse of the fetus as a patient.³ This chapter has two purposes. The first is to set out an explicit account of the ethical concept of the fetus as a patient, so that the concept is clearly stated, which allows it to be used with consistent meaning in ethical reasoning. The second is to identify major implications of this concept for obstetric management, for fetal treatment, and for innovation and research for fetal benefit.

ETHICAL CONCEPT OF THE FETUS AS A PATIENT

It may come as a surprise to readers that one reason that it took almost a decade after the

introduction of the discourse of the “fetus as a patient” to achieve an explicit account of the ethical concept of the fetus as a patient is that the general ethical concept of a human being as a patient was only implicit in clinical discourse, with its historical origins in the late 18th century long forgotten.

Historical Origins

It is commonly believed that the ethical concept of being a patient, like the other components of professional medical ethics, originates in the ethical writings attributed to Hippocrates (460–370 BC) and comes down to us through the subsequent millennia in what is known as the “Hippocratic tradition”. On this view, the subsequent history of medical ethics is but a “footnote” to the Hippocratic Corpus. Unfortunately, there are two major problems for this “footnote” view. The first problem is that there is no “Hippocratic tradition”.⁴ For example, references to the Hippocratic Oath begin to fade away in the early centuries of the Common Era. In the medical schools of the medieval universities of Western Europe, medical students did indeed take an Oath—of loyalty to their professors and their university.

The second problem is that Hippocratic medical ethics is based on a contractual relationship between the sick individual and the physician. This became the model for

medical ethics for the next two millennia. The word used in the Latin literature was *aegrotus*, or the sick person. This was frequently mistranslated into English as “patient,” suggesting a professional relationship and demonstrating the strength of the misleading belief in the “Hippocratic tradition.”

During this period, physicians struggled to compete successfully in the small market of services to the wealthy and to princes of city states. As a result, the payer had the power of the purse over physicians. By the 16th century, a literature arose to provide an ethics for this financial and political reality, in Latin *Medicus Politicus*, translated as the “politic physician.” The politic (not “political”) physician recognizes that he is subordinate to power. Success in such a relationship calls for prudence, the virtue of identifying one’s legitimate self-interests and acting to protect and promote them. In the early 18th century, the German physician-ethicist, Friedrich Hoffmann (1660–1742), expanded the virtue of prudence to become what he called “enlightened self-interest.” The prudent physician, who wants to have the confidence of the sick and to be a success financially, takes into account the interests of the sick. For example, Hoffmann argues that enlightened self-interest requires the physician to be chaste with female patients and therefore not to take sexual advantage of them, a well-recognized problem at the time.⁵

Nonetheless, not all physicians followed Hoffmann’s admonitions, and a crisis of trust developed.⁵ The sick increasingly came to the view that physicians could not be counted on to know what they were doing. This is because there were almost as many theories of disease as there were physicians. Physicians concocted and sold secret remedies emblazoned with their names, without any reliable account of the portions of the ingredients and their pharmacokinetics (in part because

there was then not even an inkling of this science). This intellectual distrust became compounded by moral distrust: the belief that physicians’ recommendations were based on their interest in lining their pockets with the sick person’s money. Typically, the sick self-diagnosed and self-treated and turned to physicians only when self-treatment (known as “self-physicking”) failed and the course of illness—or pregnancy—took a turn for the worse.

In this context in Great Britain, a new health care institution, the Royal Infirmary, was created to provide care for the working sick poor, who came from the lower social classes. Physicians were not wealthy but typically came from what today would be called the middle classes. Physicians in their daily lives would have had little or no social contact with working people, the working poor who lived in different parts of cities than the middle class. In addition, in virtue of institutional hierarchies, without which institutions cannot function, physicians gained power over the sick. Contractual ethics, the ethics of the Hippocratic Oath, and the ethic of the politic physician, *medicus politicus*, were inadequate to provide guidance for the use of this new-found power of physicians over the risk. The intellectual and moral distrust that existed in the private practice of medicine was now further compounded because the sick had no power of the purse to counter the institutional power of physicians in the infirmaries.

A Scottish physician-ethicist, John Gregory (1724–1773), who had trained in the Royal Infirmary of Edinburgh and was now teaching there as Professor of Medicine at the University of Edinburgh, came to the view that a chronic experience of intellectual and moral distrust and subjugation to potentially predatory power made the lives of the sick perilous, which then had a corrosive effect on the

character of physicians. Gregory's genius was twofold: he saw the problem for what it was and supplied a philosophically sophisticated and clinically applicable solution.⁵

Gregory's first step was to call for the practice of medicine to be based on science and for physicians to become scientifically and clinically competent. He did so because very few physicians, and fewer surgeons, based their practice on science. Gregory appealed to the scientific method of Francis Bacon (1561–1626), who called for medical practice and research to be based on what Bacon called "experience". By this, he did *not* mean the experience of an individual physician, because individual experience is hopelessly biased. Instead, Baconian experience means that clinical practice should be based on the carefully observed and reported results of natural experiments (observations of the course of disease and its outcomes) and controlled experiments (testing each element of a compound drug separately for efficacy and safety, with the goal of simplifying drugs and improving safety). This approach was explicitly designed to reduce bias and the uncontrolled clinical variation that bias creates.

To Baconian philosophy of medicine Gregory added a second step: the ethics of the Scottish moral sense theorists, especially David Hume (1711–1776). The "moral sense" was called sympathy: the natural capacity of each human being to enter into the experience of others and respond accordingly. Sympathy causes the physician to recognize the suffering of the sick and act to relieve their suffering. Sympathy-based behavior acts as a powerful antidote to the self-interest of individuals and the self-interest of merchant guilds (associations of purveyors of special services like medical care based on shared self-interest in prestige, power, and money and not to a cause larger than themselves). The Royal Colleges of the 18th century in Britain functioned

as merchant guilds under royal charters from the King.

By completing these two steps, Gregory invents the ethical concept of medicine as a profession. This concept comprises three commitments of physicians—to the scientifically and clinically competent practice of medicine; to the primacy of the patient's health-related interests and the systematically secondary status of an individual physician's self-interest; and to the primacy of the patient's health-related interests and the systematically secondary status of group self-interests. The first commitment becomes the antidote to the then-rampant intellectual distrust of physicians, while the second and third commitments become the antidote to the then-rampant moral distrust of physicians.^{5,6}

When physicians become professional practitioners, rather than entrepreneurial practitioners, by making these three commitments, the sick become patients. Before Gregory, the sick had little or no choice but to regard physicians as potential predators from which the sick needed to protect themselves (mainly by relying on self-physicking—self-diagnosis and treatment—and going to a physician only as a last resort). After Gregory, the sick come under the protection of a professional physician: someone who can be intellectually trusted to know what he was doing and morally trusted because he systematically put the health-related interests of the patient first. Put succinctly, a human being becomes a patient when he or she is presented to a physician and there exist clinical interventions that are reliably predicted to benefit that human being clinically.

Fetus as a Patient

The ethical concept of the fetus as a patient applies the general concept of being a

patient to the fetus.^{7,8} The fetus becomes a patient when it is presented to a physician and there exist clinical interventions that are reliably predicted to benefit that fetus clinically. Viability, the physiological and clinical capacity to exist ex utero, albeit with neonatal intensive care, plays a major role in the clinical application of the ethical concept of the fetus as a patient. While there are investigational interventions, there are no clinical interventions that are reliably predicted to benefit the previable fetus clinically. The management of pregnancy before viability is observational, and includes evaluation and prevention. Pre viable fetuses become patients when a pregnant woman is presented to a physician and she has not elected induced abortion and intends to complete her pregnancy in a live birth. The pregnant patient is free to withhold or withdraw the moral status of being a patient. By contrast, there are clinical interventions that are reliably predicted to benefit the viable fetus. The viable fetus becomes a patient when the pregnant woman is presented to a physician.

IMPLICATIONS OF THE ETHICAL CONCEPT OF THE FETUS AS A PATIENT

The ethical concept of the fetus as a patient has implications for clinical ethical judgment and clinical practice based on such judgment.

Autonomy-based and Beneficence-based Ethical Obligations

Clinical ethical judgment in obstetric practice is complex: the physician has ethical obligations to two patients, which are based on the ethical principle of beneficence (provide clinical management that in evidence-based clinical judgment is expected to result in net clinical benefit for the patient) and the ethical principle of respect for

autonomy (empower the patient with clinical information that she needs to participate in the informed consent process). The physician has beneficence-based and autonomy-based ethical obligations to the pregnant patient and beneficence-based ethical obligations to the fetal patient. There are no autonomy-based ethical obligations to the fetus because the fetus lacks the neurologic capacity to participate in the informed consent process.

The obstetrician must in all cases identify all three ethical obligations and, when they are in conflict with each other (which rarely occurs), provide a reasoned account for prioritizing them. This reasoning must recognize that none of the three ethical obligations is absolute, i.e. automatically takes priority over the others. Instead, each of these obligations is limited or, in the technical language of ethics, each is *prima facie*.^{7,8}

The pregnant patient also has beneficence-based ethical obligations to the fetal patient. The *prima facie* nature of these obligations means that the pregnant patient is ethically obligated only to take reasonable risk to herself for fetal benefit.

Counseling about Induced Abortion

Induced abortion (the evacuation uterus in a previable pregnancy) is governed by autonomy-based ethical obligations to the pregnant patient.⁹ There is no beneficence-based ethical obligation to the fetus when the pregnant woman withholds or withdraws the moral status of being a patient from the previable fetus. Some women may make clear from their first prenatal visit that they do want to remain pregnant. Others may express concern or hesitation about remaining pregnant, e.g. after the diagnosis of a fetal anomaly. When a pregnant patient gives an explicit or implicit indication that she may not intend to continue her pregnancy, the physician counsel the pregnant patient about the

alternative of induced abortion (consistent with applicable law) in a nondirective fashion. “Nondirective” means that this alternative should be presented and described but no recommendation made. This is because the decision to remain pregnant, while it has a medical component, is ultimately a personal decision. “Shared decision making”, precisely understood, is another name for nondirective counseling. This approach should also be taken with patients whose pregnancy has resulted from rape or incest.

Maternal-Fetal Intervention

Intervention for fetal benefit is maternal-fetal intervention, because access to the fetal patient for medical or surgical interventions occurs through the body of the pregnant patient. The use of “maternal-fetal” also has an important ethical justification: this discourse reminds the physician that ethical obligations to both the pregnant and fetal patient must be identified and balanced, as explained above.

Nondirective counseling, or shared decision making, should not be the universal approach to decision making about all maternal-fetal intervention, because the evidence-based clinical benefit can be strong. Whenever the evidence-based for any clinical intervention is strong, there is a professional responsibility to recommend it, which is known as directive counseling. For example, the physician should engage in directive counseling for cesarean delivery for intrapartum complete placenta previa and severe fetal distress. Shared decision-making risks misleading the pregnant patient about the evidence-based clinical superiority of cesarean delivery in such cases.⁸

Planned Home Birth

Directive counseling, in the form of a recommendation against a form of clinical management,

is ethically obligatory when there is evidence that the form of clinical management entails preventable, unacceptable clinical risks to the pregnant, fetal, or neonatal patient. For example, in the United States, there is very reliable evidence of increased perinatal risks of mortality and morbidity from planned home birth that can be prevented by planned hospital birth. When a woman expresses an interest in planned home birth, the physician should present the evidence for its unacceptable risks¹⁰ and recommend against it. The physician, in this directive counseling process, should be attentive to the patient’s beliefs about planned home birth and respectfully correct misperceptions about the safety of planned home birth.

When a woman nonetheless elects planned home birth and presents at the hospital for emergency obstetric management, the obstetric should follow accepted protocols and strictly avoid judgmental attitudes and verbal or other behavior based on such attitudes, which do nothing to improve the quality of patient care. In addition, obstetric teams should work diligently to improve the quality of a home-like experience of hospital delivery.¹¹

Intrapartum Management

Decision making about intrapartum management should be guided by the strength of evidence for clinical judgment about maternal or fetal benefit. When there is a reliable evidence base of such clinical benefit, the physician should make the appropriate recommendation. When the evidence base is weak, the alternative of nonintervention may be medically reasonable and therefore it should be offered along with clinical management, followed by nondirective counseling. This line of clinical ethical reasoning applies to cesarean delivery. Decision making about

cesarean delivery is typically guided by the implicit assumption that the choices are binomial. Either cesarean delivery is clearly indicated, e.g. intrapartum complete placenta previa, or it is not. This way of thinking ignores the clinical reality that there is middle ground, e.g. trial of labor after cesarean delivery of trial of labor after cesarean (TOLAC). In hospitals that meet the criteria for TOLAC, offering the pregnant patient trial of labor is medically reasonable, as is offering planned cesarean delivery, because both are well supported in evidence-based and beneficence-based clinical ethical judgment. In such clinical circumstances, thinking binomially about cesarean delivery can be clinically misleading, a risk that is managed by invoking clinical ethical reasoning.¹²

INNOVATION AND RESEARCH

Innovation and research are both forms of experimentation. A form of clinical management is experimental when, in evidence-based reasoning and on the basis of critical appraisal of clinical experience, the outcome of that form of clinical management cannot be reliably predicted. Innovation is an experiment undertaken on a patient for the clinical benefit of that patient. Research is an experiment undertaken on a group of patients to produce generalizable knowledge for the benefit of future patients.⁸

The ethics of clinical research are now very well established. Research with human subjects in all clinical areas is ethically permissible, if and only if it has been prospectively reviewed and approved for its scientific, clinical, and ethical merit by a committee with the authority to do so. In the United States, these are known as Institutional Review Boards, or IRBs, and in other countries as Research Ethics Committees or RECs. The

IRB/REC is charged with the beneficence-based responsibility to assess a protocol to determine, if its research question is clinically significant, whether the study design is appropriate for answering the research question, whether the sample size is the smallest possible (to prevent unnecessarily exposing research subjects to the risks of research), and other matters of the scientific design and execution of a research protocol. The IRB/REC also has the autonomy-based responsibility to assess the proposed informed consent process and its documentation. There are no exceptions to the requirement to seek and receive prospective review and approval of clinical research.⁸

For most of its history, innovation has occurred in all medical specialties without such prospective review and approval. In part, this was the case because innovation does not come under the definition of research and therefore under the purview of an IRB/REC. Unfortunately, the history of innovation is very mixed in its outcomes, e.g. mammary artery ligation for the management of unstable angina. As awareness of this history increased in the late 20th and early 21st centuries, the Society of University Surgeons responded to a growing literature on the ethics of innovation calling for the improvement of its quality by instituting prospective review and approval of planned innovation by a committee specifically charged with the responsibility to do so, along parallel lines with the responsibility of an IRB/REC. The goal is to improve the scientific integrity of innovation and the informed consent of patients.¹³ Both beneficence-based and autonomy-based clinical judgment support this approach to planned innovation. This means that the burden of proof is on the physician who engaged in planned innovation without prospective review and approval of its scientific, clinical, and ethical merit.

CONCLUSION

The ethical concept of the fetus as patient is essential for professionally responsible obstetric practice, innovation, and research. This concept is expressed as a set of three obligations—(1 and 2) beneficence-based and autonomy-based ethical obligations to the pregnant patient; and (3) beneficence-based ethical obligations to the fetal patient. Because none of these obligations absolute, i.e. because each of these obligations is *prima facie*, all three must be identified clearly and their implications taken into account. The result will be clinical practice, innovation, and research undertaken with professional integrity that protects both pregnant, fetal, and neonatal patients and research subjects.

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Ethical Issues in Women with HIV

Motshedisi Sebitloane

INTRODUCTION

Background: Burden of Disease

Women make up more than half of the people living with the infection worldwide. In real terms, this accounts for at least 51% of the infected population, the rest made up of men and children.¹⁻³ Of the 36.7 million people who were living with HIV in 2016 worldwide, 52% were in Sub-Saharan Africa (SSA), with 66% new infections occurring in this region per annum. Because human immunodeficiency virus (HIV) primarily spreads through sexual contact, affected women are predominantly in the reproductive age group of 15-24-year old, which accounts for more than 25% of new infections in SSA. The predominance of the HIV amongst women of the reproductive age groups means therefore that pregnancy will constantly coexist with the infection. The tragedy is that the positive serostatus is often an incidental finding during pregnancy, and so is pregnancy often unplanned in women with known HIV infection. The two scenarios mean therefore that the desirable optimal management of both conditions is often a matter of chance and luck than a grand design.

The use of highly active antiretroviral treatment (HAART) has significantly changed the landscape of HIV/AIDS disease.⁴ For women infected with HIV, the use of HAART

has restored both the hope of giving birth to a HIV uninfected child, but also that of a longer lifespan, with the possibility of bringing up a child to maturity. This has removed the argument against procreation in the backdrop of a life-threatening disease, which was prevailing before the widespread use of HAART. Additionally, it is hoped that there will be reduced discrimination and stigmatization of HIV-infected women who were often been seen as being irresponsible when desiring fertility. The argument against procreation centered on the following:⁵

- Risk of vertical transmission to the offspring (this has been significantly reduced from 15-30% without treatment, to well below 2% with the use of HAART, even in resource constraint countries⁶).
- Reduced lifespan of the potential parent(s), and the possibility of leaving behind an orphan (studies have shown improved maternal and infant outcomes with the use of HAART⁷).
- If the partners are serodiscordant, the risk of transmission to the other partner while attempting a pregnancy (HAART has recently been shown to also reduce horizontal transmission to the partner, and may therefore be used as a prevention strategy when dealing with serodiscordant couples.^{8,9}

Predisposing Factors to Increased Infection

The risk of HIV acquisition is higher amongst women than men.^{10,11} Though there are biological factors that contribute to this, most of the predisposing factors are societal, political, and economical. Therefore, most of the clinical ethical considerations on the issue (i.e. of patient autonomy, beneficence, and nonmaleficence) cannot be applied outside of the healthcare platform, however, they remain worthy of mention. In many settings where HIV is prevalent, women find themselves in subordinate relationships¹² where they are unable to negotiate risk reduction measures such as the use of condoms.¹³ There is often a culture that accepts multiple partners as a norm, or women are unable to negotiate themselves out of these polygamous relationships, due to financial and economic deprivation. The subservient role of women (particularly if married) in these societies also predisposes them to domestic violence,¹⁴ which also enhances their risk of being infected by their partners. The economic dependency of women may also limit their access to healthcare, and thus women may present late for diagnosis and care, and continued treatment of their infection may be interrupted due to resources. Despite this, studies have documented that most people who present for HIV care are women,¹⁵ and this often poses a dilemma in that they are often seen as the first one bringing news home of being HIV infected. The latter often results in women being blamed for the infection, being stigmatized, and can often be the reason for domestic violence. Since these issues play out in the communities, countries should strengthen laws, which prohibit gender violence and exploitation of women and expressly protect against discrimination based on HIV status.¹¹ While these are all societal issues, it is important

for the health practitioner to be aware of the compromised human rights conditions from where their patients come, and address these with the individual woman where possible, as this may impact on long-term access to care. There should be an understanding that many women are vulnerable, often victims, and not vectors who perpetrate the spread of the infection. The health system should be structured such that it encourages initiatives for group support and mobilization of resources, as this can improve access to care and the well-being of HIV-infected women.

Ethical Considerations in Care

In rendering sexual and reproductive healthcare to HIV-infected women, practitioners should be conversant with the issues pertaining not only to the clinical course and treatment of the disease but also ethical matters of privacy, confidentiality, and patient rights. Particular effort should be made to avoid partiality, being nonjudgmental, avoiding discrimination, and respecting patient autonomy. Practitioners may feel that patients are being irresponsible when seeking to fall pregnant while HIV infected,¹³ and may therefore withhold certain clinical interventions that would otherwise have assisted the woman. This is obviously a case of discrimination, which is defined by the United Nations as “any measure entailing an arbitrary distinction among persons depending on their confirmed or suspected HIV serostatus or state of health.”¹⁶ Part of the community and health practitioner discrimination or negative attitudes toward HIV-infected women are related to the perception on how the disease was acquired. With emphasis on the number of sexual partners as one of the major risk factors for HIV infection, it is often assumed that an infected woman has been promiscuous (further stigmatizing her), or amongst the men, the infection is often associated with the

marginalized members of society such as intravenous drug users and men who have sex with other men.¹⁷

When dealing with HIV-infected women seeking reproductive health services, the health practitioner should be impartial and inform the couples about the disease process, the risks to the fetus, and effects of the drugs on pregnancy outcome (known and unknown or potential long-term effects) in order for them to make informed and un-coerced decisions.

REPRODUCTIVE RIGHTS OF HIV-INFECTED WOMEN

The desire to procreate is inherent in many women, regardless of the societal status or their health condition. HIV infection should never be used as a reason to influence the care given to women regarding their reproductive rights and capabilities. Advice can be tailored to the general health of the patients (e.g. whether in her current clinical status, it is advisable to become pregnant) and steps taken to improve that with the use of HAART, with the ultimate aim to render the woman able to access all reproductive health assistance as other non-HIV-infected women.

Where abortion is allowed, HIV seropositivity should not be the grounds for which it is proposed by the practitioner. In countries, which allow legal termination of pregnancy, this can be accessed upon the request of the woman for any reason up to the end of the first trimester. The regulations state that beyond this and up to 20 weeks of gestation, a woman may after consultation with the doctor together agree that “her physical or mental health will be harmed, if the pregnancy continues”,¹⁸ and therefore, HIV infection is one of the conditions, which would qualify for such a scenario. The decision to terminate should be by the patient’s autonomous request, and she should not be coerced into

making it. There have been reports of HIV-infected women who have been forced to have postpartum sterilization, on the basis of their HIV status.^{19,20} This violates patient autonomy (which is defined as “the ability to make choices free from outside pressure or violence, whether mental or physical”).²¹ Further, it encourages stigmatization and discrimination on the basis of HIV status. Practitioners who enforce such are violating medical duty obligations and abusing the understanding on “beneficence” (i.e. “do good”), as they may argue that they are doing this in the effort to promote the well-being of the woman. This, however, disregards patient autonomy and also negates the principle of nonmaleficence (do no harm) by not considering the long-term impact on psychological and their social standing of such an action.

A tenuous situation such as management of a patient with advanced HIV disease, who is not on lifesaving HAART but requiring life support measures [such as in intensive care unit (ICU)], creates a difficult dilemma. A woman may present with a condition that is due to the immune system failure, since the use of HAART is known to take some time for it to improve the clinical condition, and putting her on lifesaving ICU may be seen as futile. A typical example is the patient who has not yet initiated HAART, presenting in respiratory failure due to an opportunistic chest infection related to immune deficiency, the principle of justice (rendering to the patient what is due to them) is often overridden by the consideration of the futility of the clinical status, and the practitioner’s role in the prudent allocation of limited medical resources. Putting her in ICU may result in a prolonged stay on life support machines, resulting not only in increased costs to the healthcare system but also a moral dilemma subsequently regarding whether and when

withdrawal of care would be considered. This is one situation where distributive justice has to be carefully considered. Withholding and withdrawal of medical care is a separate discussion, which is determined by patient views, and is governed by different country legislations.

HIV IN PREGNANCY

Counseling and Testing

Because of the public health impact of HIV infection, awareness of the disease is paramount to its control. This means at wide-scale community level—to health sector platform as well as at an individual level. Many will promote public health and community awareness, not only to increase prevention efforts but also to mobilize resources needed for both prevention and treatment. At a health sector level, the health practitioner has to be conversant with HIV disease and treatment, and HIV is to be central to management algorithms, especially in settings of high seroprevalence rates. It can only be seen as such if it was to be viewed as one of the many treatable (though potentially terminal) chronic diseases. This requires that the health practitioner be aware of the patient's status, and be able to respond accordingly. For this to happen, the practitioner should have a nonjudgmental outlook, where one will be able to prompt for HIV testing (i.e. provider-initiated testing), without making the patient feel that she is being suspected on certain grounds. Agreeing (and even declining) to HIV testing (following counseling) is in line for with respect for patient's autonomy, where she is made to feel responsible and accountable for her own health, being respected to make her own decisions in a dignified manner. This begins with counseling regarding the disease, the benefits of which include empowering the patient in order for

her to take charge of her own care as well as making informed decisions regarding the many facets of this care. Additionally, it is hoped that this awareness will enable her to make safer choices for herself and those close to her (such as disclosure to the partner and prevention of mother-to-child transmission). This process of informed consent before testing, which does not have to be written, is nonetheless important for all further interactions on HIV care. Informed consent principle accepts that the patient has a right to decline any test or procedure.

How to test remains a matter of debate—there are different approaches:²²

- In many instances, the patient ought to undergo “pretest and post-test” counseling before the test is performed. Pretest counseling should cover which the disease processes, its acquisition, transmission, and treatment, and is often viewed as a rate-limiting step in the care of HIV-infected individuals. The entire counseling process (pretest and post-test) is seen by some as “cumbersome” and is time-consuming, as it demands a private space and dedicated time and dedicated individual for counseling²³ (who can be any health practitioner or dedicated counselor). A model where testing is preceded by pretest counseling and informed consent is called the “opt-in” approach,^{22,24,25} and places much emphasis on the individual and her rights to self-determination, autonomy, and privacy. Because it places the responsibility on the individual, it is hoped that she will act out of a good conscience toward others and not willfully expose those close to her who are at risk of acquiring the infection (i.e. the sexual partner or the unborn child). The disadvantage of this model is that it rests squarely on the individual's understanding, frame of mind, and does

not provide a solution to ensure the protection of the greater public or the “at risk” third party (i.e. sexual partner or unborn child).

- In the “opt-out” approach, which stands to benefit more the public interest, the recommendation is that of universal testing, where an HIV test is made part of routine care, included amongst the many other tests that are performed (e.g. as part of antenatal screen). In this model, while pretest counseling is done (to the individual or as a group), consent to testing is presumed and not explicit. Therefore, the individual will have to proactively object to testing (i.e. opt-out). The appeal of the “opt-out” approach is in the backdrop of HIV-infected pregnant women, who may decline testing for various reasons, whereas the fetus is left at risk of vertical transmission, if nothing is done. For this reason, the long route of pretest counseling, and agreeing to test is taken away, and interventions can be instituted as early as possible. The proponents of this approach argue that making it part of routine screening will also take care of the increased stigma associated with the disease.^{25,26} In other settings, it has been proven that more women are eventually tested and interventions instituted early with this approach. In settings of limited resources, and late antenatal care attendance, this may yield better outcomes, provided that information on testing is still provided and maternal autonomy is still respected. The advantages include increased rates of testing and have also been shown to be widely accepted.²⁶ It also has the appeal in that while it benefits the greater public good, it still preserves the individual’s right to autonomy. The “opt-out” approach should not only be applied to certain populations, e.g.

pregnant women, as the latter are already considered the “vulnerable” population, but, for the reasons given, it should be offered to the general public.

- Another model of testing is referred to as “mandatory”, where all individuals are mandated by policy or laws to undergo testing. This in some instances may be name based or anonymous. The former can be seen as utilitarian and undermining individual’s basic human rights.^{24,27} The appeal of non-name-based mandatory testing is for public health control of the disease, mainly in high-prevalence settings. An example of a well-utilized mandatory testing the South African anonymous antenatal survey, which has been used to track the epidemic amongst pregnant women, but also used by lobbyists for resources.²⁸ Whether name based or not, it was initially discouraged in the early days of the epidemic, since there was no cure for the disease, and many countries were unable to offer lifesaving treatment. However, this has changed, as the course of the disease has been altered by use of combination antiretroviral treatment (cART), and its transmission to others is halted. There are still those who promote mandatory testing especially for premarital counseling as well as in perinatal counseling.²⁷

Coupled with the mandatory testing is the argument, whether HIV infection should be notifiable. However, this goes back to the unfavored approach of “name-based” mandatory testing. The argument for this is the greater duty toward the public and community importance in order to conduct proper surveillance on the extent of the infection in a given community, as well as to afford the authorities to plan resources for prevention and treatment. Mandatory testing also limits the ability of the patient to accept

the condition, and promotes the idea of being targeted and stigmatized. Additionally, there are no efforts in this model that support the patient to change their behavior and help to contain the disease.

Disclosure

The other issue, which centers on the knowledge of a woman's status is related to who should she disclose her status to. It is recognized that no personal and especially medical information may be shared with other members without the woman's knowledge and consent, as this is a breach of confidentiality. It should be understood that the patient should be the one to disclose to those close to her, in particular the sexual partner. However, this may bring in the issue of stigmatization, which may be real or perceived. As mentioned earlier, the notion of how the infection was acquired leads to self-judgment or judgment by others (i.e. stigmatization). Often the individual believes they will be judged by family, community, and health workers; and this in itself will deter her from testing or more importantly from disclosing. Self-stigmatization can be minimized by post-test counseling, which ideally should not be once-off following testing, but should be ongoing, with linkages to support groups where they exist. Disclosure may be associated with being discriminated upon, and even results in domestic violence where the male partner may blame the woman for the infection. No disclosure to the next of kin may be embarked on by the healthcare giver without prior discussion with the woman, and should ideally be done by her personally. If she reports to have disclosed, this should be documented. In the event that the health worker has reasons to believe she has not disclosed to the person deemed most at risk (i.e. sexual partner), despite ongoing encouragement to do so, the responsibility rests the practitioner

to inform the partner, however, the woman must still be informed that of the intentions of the practitioner.

- In a clinical practice, the information may lie open in records, discussed openly in ward rounds, etc. and therefore, the confidentiality may not be as guaranteed as hoped for beyond the health setting. It is also important to discuss with patient who among her next of kin, may have access to her clinical records. This lack of disclosure to relatives may hamper HIV documentation, and it has been noted that prevalence data may be underestimated as a result of failure to record diseases or deaths as related to HIV infection.^{24,29} This not only affects the surveillance data, but also limits prevention efforts and resource allocation.
- Lack of disclosure should not be used to ration access to services (or resources). In some instances, patients wishing to access HIV treatment would not do so unless they had disclosed or brought along someone they have disclosed their HIV status to. Though it was used in the context of a treatment support partner to ensure adherence,³⁰ this could be seen as a form of gatekeeping and may discourage many women from accessing lifesaving HAART.

ETHICAL CONSIDERATIONS IN HIV-INFECTED WOMEN SEEKING ASSISTED REPRODUCTION

In the majority of women, HIV infection is acquired sexually and therefore often co-exists with other sexually transmitted infections. The latter are known to result in tubal factor infertility. Additionally, most of the infected women may be of advanced age, and may therefore other factors impacting on reproductive ability such as anovulatory cycles and fibroids.

Whereas natural conception does not need justification to anyone,⁵ patient autonomy can be eroded upon in circumstances of assisted reproduction in HIV-infected women. The practitioner's views and biases may influence how far he/she is willing to explore possibilities of reproduction with the woman/couple. A few ethical considerations for a HIV-infected woman or couples seeking assisted reproductive techniques:

- Firstly, is assisting infertile couples who are HIV infected (particularly the woman), the best use of limited resources? While the right to procreate is a given right to every woman, the use of resources in the treatment of infertility is fraught with concerns of assisting a woman who may not live long enough to bring up the offspring until he/she reaches maturity. Even when considering that HIV/AIDS is potentially a treatable disease, which can be well-controlled with the use of HAART, there is potential for complications and deterioration. However, this would entail as in any other chronic disease. The ethical consideration would be similar to women with for example chronic diabetes, the discussion would be how well the disease is controlled, are there any complications and end-organ affectation. Therefore, the refusal to offer treatment should not be viewed as a form of discrimination on the basis of HIV status, but on the general welfare of the potential mother, and the long-term prospects of her lifespan. Since no one woman (even without any medical condition) is guaranteed a long lifespan into old age, and therefore HIV-infected women on treatment should also be given the same benefit of doubt.
- As mentioned previously, the earlier concerns regarding offering assisted reproductive technology to women/couples with HIV infection were based on the fact of no possible cure for the disease and the limited lifespan of the parent(s). However, recent therapeutic advances in the management of HIV/AIDS have enhanced the length and quality of life for HIV-infected individuals. Studies have documented a reduction in maternal mortality with the use of HAART during pregnancy, and even in nonpregnant women, increased lifespan of the infected individuals has been recorded.³¹ Together with this, the risk of vertical transmission to the offspring has been greatly reduced to below 2% in well-managed individuals. However, regardless of the best treatment, studies have further cautioned that this vertical transmission cannot be accurately predicted and completely eliminated. There is also a continued concern regarding the unknown long-term effects of the drugs on the fetus/offspring.³²
- In cases of serodiscordant couples, HAART is recommended as a means of prevention ("treatment as prevention"⁹), where studies have shown that the risk of horizontal infections can be reduced by the partner being on treatment. If the male partner is HIV infected and the woman uninfected, artificial insemination with washed sperms can be used, and successful conceptions have resulted with no risk of her seroconverting.³³ In the event of the partner being uninfected, use of HAART has been used to maximally suppress the viral load, and the risk of horizontal transmission minimized while attempting a pregnancy.
- On the other hand, the issue of assisting a woman on her own, as some women may choose not to involve the partner, invokes difficulties in how far the health worker can go. One needs to consider whether the woman has disclosed to the partner, what is the partner's status, and is he at risk. Undisclosed status can render

a tenuous situation for the practitioner (as previously discussed). Many societies dealing with assisted reproduction would insist on the serostatus of both partners being known and include this as part of their eligibility criteria for the programs offered.³⁴

CONCLUSION

Because of its most common method of spread, HIV infection has rendered women who have the infection to be one of the most stigmatized, discriminated, and vulnerable members of societies across the world. Treatment through HAART has proven the infection to be controllable, and should be managed as any chronic disease. The risk of vertical (to fetus) and horizontal (to sexual partner) has also been greatly minimized with the use of HAART. HIV-infected women should enjoy the whole package of sexual and reproductive health services, and be allowed to exercise autonomy of when and how they want to embark on a pregnancy. HIV testing with counseling empowers women to not only look after their health, but also prevent further infection to others.

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Consent in Emergency Obstetrics

Michael S Marsh

INTRODUCTION

It is universally accepted in bioethics that doctors and other medical professionals are obliged to obtain the informed consent of their patients. Informed consent is required because patients have the moral right to autonomy in furthering the pursuit of their goals. Although guidelines for informed consent in obstetrics from national and international organizations seem straightforward, the few studies of the effectiveness of informed consent both in obstetrics and other settings suggests that the process is often flawed, more so in the acute situation. In part this is explained by well-established fallibilities in human reasoning. “Consent, then, is a messy business”,¹ and in acute obstetrics, it is more so. Recent developments in improving the consent procedure may lead to more robust practice in the future.

INFORMED CONSENT

The notion of informed consent has been a key concept in medical law in the US and elsewhere since the California Court of Appeals decision in the case of *Salgo v Leland Stanford Jr University Board of Trustees* in 1957.² In this landmark case, the attorney Paul G Gebhard used “informed consent” as a technical term for the first time. The patient, Martin Salgo, presented with a suspected

aortic thrombosis and was recommended by his surgeon to have diagnostic aortography. After the aortography, the patient sustained a permanent paralysis. Despite the acknowledgment that this was a risk inherent of the procedure, the physicians admitted that they had not warned their patient of that risk. The court ruled that a physician violates his duty to his patient if he withholds facts that are needed to form the basis of an informed consent by the patient to the proposed treatment.³

Current national guidelines in Obstetrics and Gynecology across the world reflect this change in emphasis concerning how a patient is treated and include similar components for informed consent, e.g. “before seeking a woman’s consent for a test, treatment, intervention, or operation, you should ensure that she is fully informed, understands the nature of the condition for which it is being proposed, its prognosis, likely consequences, and the risks of receiving no treatment, as well as any reasonable or accepted alternative treatments”. Royal College of Obstetricians and Gynaecologists (RCOG) 2015,⁴ the recent controversial decision of the UK Supreme Court in *Montgomery versus Lanarkshire Health Board*,⁵ signaled a move away from a “doctor knows best” approach to what is disclosed when obtaining consent to one that focuses on disclosing information to which

particular patients would attach significance. For nearly 30 years, English and Scottish law on informed consent was formally out of step with most of the common law world. The Montgomery ruling trumped the decision of the House of Lords in Sidaway,⁶ which appeared to embed into UK law the paternalist principle that how much doctors told patients about the risks, benefits, and alternatives of the proposed medical treatment was a matter to be decided by the reasonable doctor. It has suggested that the recent Montgomery decision will make little difference to the current nonpaternalistic process of consent that has already evolved in the UK⁷ and it may bring the consent procedures more into line with US practice. However, the legal situation concerning consent in the US is not consistent across the Union. “Because ethical requirements and legal requirements cannot be equated, physicians are advised to acquaint themselves with federal and state legal requirements for informed consent”. American College of Obstetricians and Gynecologists (ACOG) 2009,⁸ and of course such differences will occur across the globe. The international body International Federation of Gynecology and Obstetrics (FIGO) summarizes the components of informed consent as follows:

- Informed consent is a consent obtained freely, without threats or improper inducements, after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient on:
 - The diagnostic assessment
 - The purpose, method, likely duration, and expected benefit of the proposed treatment
 - Alternative modes of treatment, including those less intrusive
 - Possible pain or discomfort, risks, and side effects of the proposed treatment.⁹

Guidelines concerning informed consent in an emergency in obstetrics are less consistent. The RCOG guidelines^{4,10} state that:

- Prior to emergency procedures, there is scope to allow verbal consent to be obtained when it is considered to be in the interest of the woman or baby. However, if time allows, written consent should be obtained for all such operations under general or regional anesthesia. In the emergency situation, verbal consent should be obtained, which should be witnessed by another care professional. Obstetricians and the witness to verbal consent must record the decision and the reasons for proceeding to any emergency delivery without written consent.

The ACOG adds that:

- A substituted judgment or a judgment on the basis of prior informed consent can be made with confidence if care has been taken beforehand to learn the patient's wishes. This signals the importance of early communication, so that what a patient would choose in a developing situation is known—so that, indeed, it remains possible to respect the self-determination that informed consent represents.⁸

The overuse of guidelines and standardized forms in the obtaining of consent may lead to consent becoming overly proceduralized, a tick box exercise that exists primarily to ensure that medical practice is aligned with prevailing professional requirements. Consent may shift from being used as a noun to being used as a verb. Doctors and medical students often talk about “consenting” their patients, as a distinct and abstracted action. It has been proposed that this shift can adversely affect a healthcare encounter, depersonalizing the delivery of care, and decreasing the quality of communication between doctor and patient.¹¹ Within the

context of consent in the medical research setting, this approach to consent in practice has been described as “empty ethics,”¹² where the activity of obtaining consent from a research participant is removed from a real-world context.

TIME AVAILABLE FOR CONSENT IN AN EMERGENCY

The time pressures involved in obtaining consent in an obstetric emergency are obviously greater than for elective procedures, but there has been surprisingly little published evidence concerning the time available for consent in such situations, although the time pressures involved are self-evident to practicing obstetricians. In a recent study of the time available for consent for cesarean section (CS), Salmeen and Brincat¹³ retrospectively reviewed the charts of review of 90 cases of CS during labor to determine the time that was available to obtain consent. The median consent time was 48 minutes (interquartile range is 25–72 minutes) and 29% of patients delivered less than 30 minutes after consent. When adjusted for potential confounders, the odds of delivering less than 30 minutes after consent were 4.7 times higher (95% confidence interval 1.4–15.2, $P = 0.01$) among women who underwent CS for abnormalities of the fetal heart rate than for women who underwent CS for other indications. When consent time was assessed in a dichotomous fashion, 29% had a consent time of less than 30 minutes and 10% of patients had a consent time of less than 15 minutes. Their study confirms that the practice of obtaining informed consent at the time when the decision for emergency CS is made is unlikely to provide sufficient time for obtaining informed consent. The same is likely to apply to other obstetric emergency procedures such as instrumental delivery and

management of severe postpartum hemorrhage (PPH).

EVIDENCE FOR THE EFFECTIVENESS OF CONSENT

Evidence concerning the effectiveness of consent is derived from the study of consent used in both the clinical setting and in research. Patient “satisfaction” with the consent process is likely to be a poor proxy for understanding of what has occurred in the consent process and effectiveness of consent. Studies and meta-analysis that include such studies with this endpoint¹⁴ are likely to give misleadingly reassuring results about the effectiveness of the consent process, although they may indicate the risk of subsequent legal action, as this is higher when the patient is dissatisfied with the consent process. More important endpoints of studies of the consent process may be the recollection of what has happened and the ability of patients to recall some of the factual components of the consent process after the event. Patient satisfaction with the consent process has been shown not to correlate with such measures of effective consent.¹⁵

Studies of the effectiveness on consent for elective procedures in a variety of medical specialties have consistently found that patients have a poor ability to recall the details of the consent interview^{16–21} and from the sparse available data, it seems clear that recall is lower after emergency surgery than after elective procedures.^{15,17,22} The amount of data concerning the effectiveness of consent in emergency obstetrics is particularly sparse and often relies on unvalidated questionnaires.

Akkad and coworkers²⁰ performed a detailed questionnaire study of 1,006 consecutive patients undergoing elective or emergency surgery in obstetrics and gynecology. They examined patients’ experience and

recall of the consent process, their overall satisfaction, and their views on what is important for adequate consent. The response rate for returned questionnaires was 71%. There were significant differences in responses between patients undergoing elective ($n = 499$) or emergency surgery ($n = 233$). Patients undergoing emergency surgery were less likely to have read (51% vs 83%, OR: 0.22) or understood (49% vs 71%, OR: 0.39) the consent form. In both groups, the two leading reasons for not reading the consent form were having had a "verbal explanation" and "trust in the doctor". Those who underwent emergency surgery were more likely to report feeling frightened by signing the consent form (55% vs 33%, OR: 2.52). Over a fifth (22%) of elective and over a third (36%) of emergency patients either did not know who asked them to give consent, or indicated that they believed that it was a member of the anesthetic or nursing/midwifery staff. A significant minority of emergency patients (23%) perceived the length of time available to consider the forms insufficient, as did just under a fifth (18%) of elective patients. Emergency patients were more likely to report they felt they had no choice about signing the consent form (40% vs 24%, OR: 2.11), and that they would have signed regardless of its content (37% vs 15%, OR: 3.14). Overall, comparing elective and emergency surgery, significantly more patients undergoing elective surgery reported satisfaction with the consent process (80% versus 63%). Patients were more likely to report satisfaction, if they read (OR: 1.80) and agreed with (OR: 3.49) the consent form, and if someone checked that they understood (OR: 3.09). This study was conducted at a hospital with a clear and widely disseminated consent policy, implemented following the publication of the UK Department of Health guidelines,²³ and local audit had apparently demonstrated good adherence to procedures.

To investigate women's recall of information provided during the consent process for CS, Odumosu and coworkers²⁴ used a prospective questionnaire-based design to study 554 women after delivery. Participants were required to list the risks that they recalled from the consent discussion about CS 24 hours postsurgery. Those women who did not recall the risks associated with the procedure (group 1, $n = 140$) were compared with those who did recall this information (group 2, $n = 414$). Women in group 1 were four times more likely to have undergone an emergency CS than group 2 (OR: 4; 95% CI, 2.5–6.2). Women in group 2 were more likely to have higher than secondary level education, seven times more likely to have understood the explanation of the procedure (OR 6.9; 95% CI, 3.3–14.2), and nine times more likely to recall that the risks had been explained (OR: 9.4; 95% CI, 5.2–17.1). More women in group 1 stated that they would have liked to receive an information leaflet about CS at the first prenatal visit. A quarter of the women did not recall any risks associated with CS shortly after the procedure, and these women were less likely to understand or recall the details of the consent discussion.

Trauma patients may provide a proxy for laboring women who require an emergency procedure. Bhangu et al.¹⁵ assessed the differences in patient recall of the consent process and desire for further information by performing a comparative analysis of patients who had undergone orthopedic trauma and elective surgery. Information from 41 consecutive elective operations and 40 consecutive trauma operations was collected on the first postoperative day. 100% of elective patients and 90% of trauma patients knew what operation they had received, but recall of complications explained during consent was poor, and was significantly lower in trauma patients compared with elective patients (62% vs 22%,

$P < 0.001$). After surgery, 30% of trauma patients desired more information about their operation compared to 12% of elective patients ($P = 0.049$). There was no significant difference in overall satisfaction with the consent process between the two groups.

Even an attending person may have poor recall of the consent process in an emergency. Li and coworkers²⁵ prospectively evaluated parental retention of possible surgical complications in the parents of children undergoing emergency laparoscopic appendectomy. Parents were informed about seven potential complications of laparoscopic appendectomy. They were asked to recall this list immediately after the consent process (immediate recall—IR) and before discharge from inpatient stay (delayed recall—DR). A score (0–7) was awarded indicating the number of correct answers. For each recall, parents were also reminded about the complications they omitted (prompted recall). One surgeon administered all consent procedures in person. 21 mothers and 10 fathers were recruited. Nine (29%) had university or postgraduate education. The median score for IR was 2 (0–6). Five (16%) parents scored 0. Upon prompting after IR, 20 (65%) parents had no recollection of at least one complication. The median score for DR was 2 (0–7), while seven (23%) parents scored 0. At prompting after DR, 25 (81%) had no memory of at least one complication. Eight (26%) demonstrated improved DR scores. The scores were not related to patient demographics or time between interviews.

It seems that even in the setting of research the consent process in the acute situation performs poorly. For example in the study of Gammelgaard and coworkers,²⁶ only 28% of participating patients read the information leaflet before making a decision, and 25% did not read it at all.

A very recent qualitative study used in-depth interviews with women who did and did not give consent at the time of their recruitment to the WOMAN Trial (World Maternal Antifibrinolytic Trial),²⁷ a study which examined the effect of tranexamic acid and the risk of death from PPH. In their follow-up qualitative study, Houghton and coworkers²⁸ interviewed 15 women who took part in the trial with the aim of determining facilitators and barriers to successful recruitment during obstetric emergencies. Their findings provide useful information about the consent process in obstetric emergencies. Using accepted methods of qualitative analysis,²⁹ three themes emerged—(1) “too much to process”; (2) “quality of relationships”; and (3) “making it right.” Quotes from the women concerning the theme of “too much process” included comments such as “They could have given me a piece of paper to say I was signing my mortgage away. The signing thing, it’s just it seems quite pointless really” and “I think he [the Doctor] explained that it was a trial to do with stemming blood loss, but that was all a bit hazy. I was sobbing. I actually remember saying am I going to die? I didn’t really know at the time what I was saying yes to.” Regarding the theme of “quality of relationships”, with the exception of one woman, the interviews demonstrated considerable trust in professional expertise. Many women offered suggestions for improvements. Their ideas included providing more information during pregnancy or in early labor either in writing or during an individual or group discussion.

The studies above suggest that there are important problems in the current procedures for informed consent, more so in emergency situation, and indicate that different types of patients may have different consent requirements. This is in contrast to the current approach of standardizing the consent process.

IMPROVING OR ADJUSTING THE CONSENT PROCESS

It has been suggested that well-described fallibilities in human reasoning will always make the consent process difficult, both in the acute and nonacute setting, and that “if we can redesign the informed consent procedure, so that it is sensitive to the evidence regarding the fallibilities of human reasoning without compromising autonomy (perhaps even while increasing it), it would be unethical not to do so”³⁰

Such fallibilities in reasoning include—myopia for the future, in which individuals typically discount the future for the present, and can do so to differing extents that vary with time;³¹ motivated reasoning, in which decisions are strongly influenced by personal past behavior;^{32,33} defects in affective forecasting in which people overestimate the effects of events and changes in circumstances on their level of well-being,^{34,35} and defects in affective recall, with poor prediction of how future events will make us feel and how past events made us feel.³⁶⁻³⁸

These defects have led some to recommend introducing informed consent specialists,³⁰ who would receive special training in human reasoning and would be taught to be on the lookout for and explain to patients the major pathologies outlined above. A more pragmatic approach would be to train these techniques to those who prepare written consent forms and to those frontline clinicians who obtain consent in the elective and acute setting.

Others have suggested that there should be more emphasis on specific verbal consent techniques,³⁹⁻⁴¹ but oral consent is unlikely to replace written information in the nonacute setting, as studies have demonstrated that adult patients have poor retention of preoperative information presented

by verbal communication only.⁴²⁻⁴⁵ Repeated verbal information may be important. Fink and coworkers⁴⁶ demonstrated that short consent conversations were associated with less comprehension but that the repeat-back technique is associated with improved comprehension but increased time in the consent process.

DEFERRED CONSENT

Deferred consent is a process in which the clinical or study procedures are initiated without consent as soon as they are deemed to be needed, and written consent is sought later from the patient or surrogate decision maker as soon as is possible. It has been used and evaluated chiefly in the context of trials in emergency medicine⁴⁷⁻⁴⁹ and in pediatrics.^{50,51} However, in emergency obstetric trials, deferred consent had only been explored hypothetically⁵² and the use of a verbal consent procedures within a peripartum trial has recently been reported as being associated with an understandable degree of anxiety amongst professionals.⁵³

OTHER TECHNIQUES TO IMPROVE THE CONSENT PROCESS

A variety of audiovisual and computer-based educational strategies has been used to try and improve understanding and retention of information before elective procedures. Those methods that have been shown to be of use in adult patients include pamphlets and graphic materials, video tuition, computer-based interactive videos, CD-ROM (compact disk read-only memory), and internet applications.^{43,44,54-62}

Although many of the preoperative educational strategies used for elective procedures have limited application in most emergency obstetric settings, innovative use

of audiovisual and computer-based methods may be of value in the antenatal period. Aside from language difficulties, it must be appreciated that because the doctrine of informed consent is rooted in western philosophical tradition there may be inherent problems in using these techniques for patients in minority ethnic communities, which do not have such traditions.⁶³

A SUGGESTED APPROACH TO CONSENT IN EXTREMIS

It is difficult to see how informed consent in women requiring emergency obstetric surgery cannot be attained without effective preoperative patient education, and yet in some developed world settings discussion of obstetric complications in the antenatal period is frowned upon. As a junior obstetrician, the author was allowed to be part of the midwifery-led antenatal preparations classes and discussed the procedures that obstetricians may have to unexpectedly perform as an emergency in normal laboring women. This seemed to inform and reassure the women who attended such classes. Perhaps, this education made the labors of these women and job of my colleagues easier when they had to obtain consent to perform these procedures. Such formal involvement of obstetricians and other healthcare professionals in explaining labor complications in the antenatal period has become much less common, and in some circles is dismissed as medicalization of a normal process. Given that even very “low-risk” women have about a 10% risk of instrumental delivery and a 20% risk of CS, it seems illogical not to make the job of informed consent in an emergency more straightforward by elective antenatal patient education. There is evidence, as outlined above, that this would be so. We as obstetricians have an

enormous advantage over our colleagues in other surgical specialties because we have the ability to have contact with all our potential emergency patients during the antenatal period. In addition, we can often predict which women may require emergency treatment. It is a shame that over the last 30 years in some settings the opportunity to take advantage of this chance to prepare women for emergency treatment has been abandoned.

A modern ethically formalized incarnation of this approach is the concept of preventive ethics, introduced in the USA in 1990.⁶⁴ A preventive ethics approach creates the opportunity to identify and resolve potential conflicts about obstetric emergency intervention by having discussions with the patient about possible interventions in labor before the need for intervention arises. These discussions are similar to those that would occur during the consent process. Standardized, universal informed consent discussions by suitably trained personnel about medical interventions in labor during routine antenatal care as well as at times during labor when such interventions become more likely [e.g. when labor progress is slow or the cardiotocography (CTG) first becomes abnormal] seem an appropriate possible solution to the problems outlined above.

PRACTICE POINTS

As part of routine antenatal care, every pregnant woman should be informed of the risk of emergency cesarean delivery, instrumental delivery and postpartum hemorrhage using local, regional, or national data.

As part of routine antenatal care, every pregnant woman should be made aware that a low-risk pregnancy could change rapidly into a high-risk pregnancy during the peripartum period.

As part of routine antenatal care, every pregnant woman should be made aware that cesarean delivery or other emergency procedures may become necessary for either maternal or fetal indications.

As part of routine antenatal care, health-care professionals should elicit the patient's attitudes about emergency interventions in labor and tailor subsequent information accordingly. Such discussion prepares women for the immediacy and urgency of both expected and unexpected intrapartum complications, lays the foundation for the rapid decision-making, and is likely to improve any informed consent process that might become necessary.

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Section 2

Research

CHAPTER

Ethical and Legal Concerns in Uterine Transplantation

Bernard M Dickens



Ethical and Legal Concerns in Uterine Transplantation

Bernard M Dickens

INTRODUCTION

The global incidence of infertility is difficult if not impossible to determine or to estimate reliably, because of different definitions of infertility and varied regional, national, and sub-national means and resources for calculation. The World Health Organization (WHO) has estimated a stable worldwide population of 48.5 million infertile people,¹ but their identification and distribution can be approached only by regional and local studies and approximations. Individuals' quests for parenthood are affected not only by their reproductive physiology, including their age, but also by their social circumstances and opportunities, including their perceptions of the economic and related means available to them to undertake responsible parenthood. Distinctions are also drawn between primary infertility, marked by involuntary childlessness, and secondary infertility, occurring when a person who has had a child is incapable of having a subsequent wanted child, perhaps later in life or with a new partner.

Concerned though gynecologists might be, as conscientious and compassionate citizens and community members, with social barriers to wanted parenthood, such as when individuals lack appropriate partners with whom to seek to achieve parenthood, their primary professional means to assist individuals' hopes for parenthood are through

medical procedures they may undertake to promote their patients' parental ambitions. A confounding factor is that a couple frustrated by their inability to conceive the child they want with each other may be composed of two individuals both of whom might naturally have children with other partners. Innumerable instances are recorded of couples who separated after unsuccessful medical treatment to overcome their perceived infertility each entering new relationships in which they have children in the course of nature without medical intervention.

Medical and biological causes of infertility are numerous and might be complex to diagnose and treat, but a more obvious cause of female infertility is absence of a functional uterus in a female of reproductive age. A female might be born without a uterus, such as in Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, or suffer an injury or impairment including iatrogenic removal of the organ that deprives her of a uterus capable of normal function. Historically, adoption of a genetically unrelated child might be an option where adoption of abandoned or otherwise available children is socially acceptable, and more recently, surrogate gestation might provide women capable of ovulation with their own genetic offspring. Such strategies to relieve childlessness would not, of course, relieve affected individuals' underlying infertility.

Most recently, however, uterine transplantation has been pioneered to afford women suffering uterine factor infertility (UFI) the prospect of gestating and delivering their own genetically related children.

Whether UFI or other sources of infertility should be considered a “disease” raises challenging ethical concerns, and might have legal implications regarding, for instance, health service funding, health insurance coverage, and liability for conditions from which infertility results. What may be described as the psychological, attitudinal, or relational aspect of infertility arises in contrasting a normally healthy individual or couple who intends not to have children with those who are physiologically identical who keenly want children but find that, for whatever reason, they cannot. The former would not regard themselves, or be regarded by others, as having a disease. Might their physiologically identical peers who cannot have the children they desire be regarded as affected by a disease?

Infertility among those who want to have children has been recognized as a disease by the WHO² and, for instance, the Inter-American Court of Human Rights.³ In many cases, infertility might well be a consequence of disease or be disease related, but whether infertility should be universally considered a disease in itself, unaffected by any diagnosable pathology, is contentious.⁴ The diagnostic category of “unexplained infertility” occurs in an estimated 15% of cases affecting women unable to conceive after 12 months of regular, unprotected sexual intercourse, and after 6 months in women aged 35 and older.

For purposes of medical care and funding of healthcare services, it may be prudent and convenient to categorize this alone as a disease, but the category lacks pathological substance; absence of a medical, biological, or nonsocial explanation, such as lack of a suitable partner, is not itself a disease.

However, accepting that “we cannot reach agreement over whether infertility is a disease, even with our best theories of disease,”⁴ the frustration of a woman who lacks a functional uterus when she is otherwise situated to bear a child she wants during what are usually regarded as her reproductive years can be considered an impairment of her “health”. This is described and perhaps idealized in the Constitution of the WHO as “a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity”⁵ that merits available care.

What care gynecologists can offer such a woman as a professional service remains relatively limited. Adoption of an abandoned or otherwise available child may be an option for involuntary childlessness that some social agencies might offer, including as an altruistic act of charity toward the child, but it is not excessively narcissistic or selfish for individuals to want to rear children who share and can perpetuate their own genetic lineage. This might be achieved for an infertile woman who is able to provide her ova for in vitro fertilization (IVF), by her partner’s or donated sperm, through another woman’s surrogate gestation of the resulting embryo and surrender of the child upon its birth.

However, this strategy addresses childlessness, not infertility, and is legally unaccommodated in many legal systems and restricted or prohibited, even when financially unrewarded, in others. Where accessible, provision of their gametes can afford relief for women who lack functional uteruses (the English plural, *pace* the Latin “uteri”), and for couples socially infertile by living in same-sex unions, both female and male. Indeed, among females in same-sex unions, shared motherhood might be achieved by one partner, whether or not capable of bearing her child, giving ova for IVF with donated sperm and her partner gestating the child,

to be jointly reared by the two women who can each claim to be its mother, even when prevailing law allows only one of them to be recognized as such.⁶

This is the framework into which the prospect of uterine transplantation to overcome UFI has recently been introduced, under research protocols aimed toward eventual availability of transplantation as a therapeutic option.

UTERUS TRANSPLANTATION

Transplantation of a human uterus might be analogized to transplantation of other solid human organs, such as hearts, kidneys, livers, and lungs, but with distinctive characteristics. The uterus is not itself an organ essential to recipients' long-term survival, and transplantation would be temporary, for gestation leading to childbirth and removal of the uterus after its purpose has been accomplished. Pioneering initiatives in human uterus transplantation were recorded in Saudi Arabia in April, 2000 and Turkey in August, 2011, with some but limited effect.⁷ The procedure was most successfully undertaken, however, by the medical team under Dr Matts Brannstrom, at Sahlgrenska University Hospital in Gothenburg, Sweden, following rigorous appropriate animal research. Birth of a healthy neonate was reported in 2015, in extensive detail, after the health status of the child, born slightly prematurely, had been confirmed.⁸ This furnishes the model for initial analysis of ethical and legal implications of uterus transplantation.⁹

However, further international developments will warrant attention and caution. In the aftermath of announcement of the historic first successful heart-transplant, by Dr Christiaan Barnard in Cape Town, South Africa, and repetition by a well-prepared team in the US, "within months cardiac transplantations had taken place as far afield

as Japan, Venezuela, and Czechoslovakia—often in hospitals without the experience essential for such a complex undertaking," with disappointing results.¹⁰ Failure to learn from this experience of underprepared surgeons and their supporting teams, hospitals and universities seeking the acclaim and rewards of pioneering success without the depth of preparatory animal studies the Gothenburg team had conducted over many years, is liable to frustrate and deceive their patients and live organ donors, and cause their communities to waste resources and talents in premature and futile quests for cutting-edge innovation.

The Swedish team introduced their experience by showing the extent of the impairment uterus transplantation is designed to relieve, observing that in the UK, more than 12,000 women of childbearing age are thought to have absolute UFI.⁸ In the US, it was estimated in 2013 that 9.5 million of 62 million women of reproductive age (15–44) have some form of UFI.⁷ Numbers will become apparent among the younger age group when they propose to build their families. The Swedish research team ambitiously claimed that their success "opens up the possibility to treat the many young women with UFI worldwide"⁸

In the Swedish study, the mother of the neonate was one of nine women the regional ethics board of the University of Gothenburg had approved to enter a clinical trial of uterus transplantation. Approval was built on more than a decade of research with several animal species, ranging from rodents to nonhuman primates. The mother had been aged 35 years at the time of transplantation, and was affected by congenital absence of a uterus. The uterus donor was aged 61 years, and had delivered two children of her own. She was unrelated to the recipient, but was a close family friend.

The process began with the prospective mother's ova and her partner's sperm being combined for IVF, to establish that their gametes were fertile, and resulting embryos were cryopreserved. Uterine transplantation was then undertaken, and about a year later an embryo was transferred in utero. The pregnancy was normal, but at just under 32 weeks, the patient was admitted to the hospital's obstetrics division because of preeclampsia. At 16 hours after admission, a cesarean delivery was undertaken and a male neonate weighing 1,775 g was delivered. The mother was in good condition the day after delivery, and the neonate's first postnatal week was uneventful. He was normal for gestational age and required only phototherapy and room air.⁸ He was discharged from the neonatal unit 16 days after birth in good health, and weighed 2,040 g at 21 days after delivery.

Two of the nine women the university ethics board approved for transplantation had their transplanted uteruses removed because of complications, but the other six in the study received transfer of their IVF-created embryos, and two were expected to give birth by the end of 2015. All women proceeding in the study were to receive a second of their embryos to attempt a second pregnancy if they chose, and in all but the first instance, donors of uteruses were preferred to be relatives. As the transplant team explained, "in the present study, the live donor was a close family friend of the recipient, in contrast with the other donors of our study cohort who were all family members. Our patient's first choice of donor was her mother, but blood group incompatibility prevented her from taking part in the study"⁸

Following publication of the successful surgery in Sweden, several other countries disclosed their intentions to undertake uterus transplantations, such as at the Queen Charlotte's and Chelsea Hospital in London, UK,

where a clinical trial involving 10 transplants from brain dead donors was approved, but funding, of half a million pounds, remained to be secured.¹¹ In December, 2017, more positively, it was reported that in Dallas, Texas, at the Baylor University Medical Center, the first baby was born in the US from a transplanted uterus.¹² This was a success in a study of four patients, the other three transplanted uteruses being removed due to insufficient blood flow.

These instances show how many medical factors must be taken into account in contemplating entering this complex medical and surgical area. The instances are additionally instructive, however, in showing a range of ethical and legal factors that must be taken into account. These include organ donation by related and analogous donors, such as close friends of families, donation by strangers, whether identified or anonymous, and cadaveric donation, and the terms on which any donations might be ethically and legally acceptable. Within research protocols and, should transplantation become a therapeutic option, in clinical practice, further concerns are selection of women seeking transplantation, and management of donated organs between recovery from donors and implantation in recipients, and their eventual removal from recipients.

LIVE-RELATED DONATION

It has been seen that the Swedish study approved donation by a close family friend of the recipient's as being analogous to donation by a member of her family. This seems reasonable, because of the common sympathy and compassion among family members and close friends. Indeed, the bonds of mutuality of sentiment and expressions of altruism between friends may be more spontaneous and authentic than among family members,

because the latter who are eligible donors may feel some sense of obligation, to recipients and/or other family members, that does not affect relationships between friends unrelated by genetic or marital ties. The recipient's mother was unsuitable as a donor due to blood group incompatibility, but candidate donors must be suitable in many other ways than blood group compatibility.

In the social context, donors must be women who have shown that their own uterus is capable of normal function, usually evidenced by having previously had normal pregnancies, and are able psychologically to accept that they will be unable to bear any subsequent children of their own. Clinically, they must be free of pathological disorders of the uterus, particularly any that might be related to precancerous disorders. Further, lifestyle choices, such as use of tobacco products, or alcohol or drug misuse, might disqualify prospective donors.

Removal of a live woman's uterus for transplantation is unlike a routine hysterectomy, because the organ must remain intact and functional. This involves highly invasive, complex, and hazardous procedures that present a full range of irreducible levels of risk, especially to delicate, sensitive organs, tissues and pathways of body fluids. The dedication of women to subject themselves to such discomforts and risks so that others might bear children might appear to exceed commonplace altruism, and be laudable at the highest level. It might accordingly be uncharitable or churlish in ethics or law to raise concerns about donors' motivations. The gratification of seeing one's sacrifice result in a loved formerly infertile family member or close friend nursing the newborn she has borne and delivered is no doubt immeasurable, but ethics and law can be compelled to analyze the transaction unsentimentally.

An ethical concern is that, in tight-knit personal relationships, individuals might feel under familial or social pressure to act against their own interests or preferences for the benefit of others emotionally close to them, taking risks or making sacrifices they would not for more distant acquaintances. An associated possibility is that others in such relationships, including prospective organ recipients and, for instance, parents of daughters, one with UFI and another a suitable donor, may, perhaps subconsciously, influence or condition potential donors to feel obliged to offer donation. Such donors' consent to bear all that donation entails does not offend the legal principle that consent to medical interventions be freely given, without threat, pressure or undue influence, because any such vitiating factor comes not from surgical, medical, or comparable personnel but from prospective donors' familial or social environments, from which healthcare professionals are not required to insulate or isolate them.¹³

If service providers find that prospective donors are really reluctant or uncertain about taking the risks and discomfort of donation, they might ethically assess them as unsuitable to donate, perhaps on vaguely specified grounds. They might also give general health grounds, remembering the WHO characterization of health as a state of "physical, mental, and social well-being". The claim, for instance, of devoted mothers that "there is nothing they would not do" for their children, and their hopes to have their grandchildren, could require that they be objectively counseled about risks to themselves and, perhaps, dependent others of their uterus donation, so that they can make a realistic judgment of competing risks of donation and prospective benefits.

Laws of historical origin may limit individuals' choices to risk their lives or continuing

health and capacity to discharge communal responsibilities, for instance in not allowing them voluntarily to maim themselves,¹⁴ but now usually allow living people to make altruistic donations of their nonvital body materials, including solid organs like kidneys. Uterus donation fits into accepted practices of organ donation that modern states accommodate and, within limits, might encourage. The key to acceptance, however, is that donation not be induced by payment or reward; that is, that “donation” not be a sale or part of a commercial transaction, such as payment of a debt.

There is widespread popular fear, sometimes amounting to disgust, reflected in prohibitory ethical principles and laws, that human organs or body parts, from living or cadaveric sources, could become market commodities or objects of trade. Giving part of one’s body for payment has been analogized to prostitution. Prohibition of payment leaves those requiring organs for transplantation dependent on altruistic donors such as family members. For instance, where public blood transfusion services do not exist, a patient whose care would draw on a health facility’s blood bank might be required to replenish the bank through donations from others, who are often family members. This is the tradition followed in the Swedish clinical study, which looked first to family members to donate transplantable uteruses, if they were suitable.

The prohibition of acquiring transplantable organs through trade exchanges, in financial payments or in kind, is confounded when prospective recipients are dependent on the benevolence of family members and close friends. Networks of family members and close friends often maintain reciprocal relationships of benevolence expressed in the exchange of gifts. Such exchanges, for instance at birthdays and seasonal celebrations, are

outside the impersonal barter of exchange, usually of money, for goods and services in commerce or trade. The obvious hope of a mother’s gift of her uterus to her daughter is to receive the reciprocal gift of a grandchild.

However, gifts within close relationships might be given in more material forms, including gifts of money. This raises ethical and legal concerns of whether gift exchanges within families and friendship networks, in which organ donation occurs or more widely, justify external monitoring. Reciprocation of an intra-family gift of a transplantable organ might exceed a token of gratitude, and include excessive generosity that could be construed as a payment. This may arise, for instance, if a sister with a grown child donates her uterus to her younger infertile sister who subsequently pays education expenses for her sister’s child.

Reciprocating donation of body material or services, such as an organ or by intrafamilial surrogate motherhood, with a comparatively modest gift to express gratitude, has been described as “rewarded gifting.”¹⁵ The key to acceptability in this practice is that the reciprocal gifts are of clearly unequal value. When a family member donates her organ such as a uterus, and a reciprocal gift of a relatively trivial nature is spontaneously given by or on behalf of the recipient in acknowledgement of gratitude, this provides no hint of a commercial transaction. When strangers describe as rewarded gifting an exchange of prearranged “gifts” of roughly comparable value, this might appear ethically and legally suspect as a commodified transaction. The question of substantive or proportionate reciprocal gifts or exchanges is more acute when gifts are made or offered between strangers, although regarding both family members and strangers, difficult problems might arise of monitoring and enforcing ethical and legal regulations.

LIVE-UNRELATED DONATION

A feature of some societies is that when people who are celebrities in their communities, such as public entertainers, sports players, and others who are prominent, popular, and admired, are revealed as ill and in need of organs for implantation, a number of unrelated sympathizers will come forward with altruistic offers to donate the needed organs. Altruistic donation is usually offered for less conspicuous recipients, but almost invariably demand by members of the general population for transplantable solid organs exceeds the supply. It was reported that when in the 2007–08 period a center in the US received institutional approval to recruit females with UFI to study possibilities of uterine transplantation from cadavers, over 500 women applied.⁷

It may be doubted that so many women would as quickly volunteer to be live uterus donors to these applicants. Nevertheless, individuals are inspired to make genuinely altruistic donations of organs while they are alive, either to designated recipients or to recipients they do not know, and may never know. Philosophical arguments have been advanced that altruistic donation to unspecified recipients can be a source of gratification to donors.¹⁶ Prevailing ethics and many laws allow live and cadaveric organ donation on only an altruistic basis, but it is widely recognized that legal prohibitions on payments are evaded, often with impunity, and that markets and trafficking in human organs exist worldwide, generating a vast ethical, legal, medical, anthropological, and other including multidisciplinary literature.¹⁷ The ethical and legal implication for gynecologists and related practitioners is the duty to be aware and vigilant, lest they may inadvertently become complicit in unethical and unlawful removal, implantation, and/or management of trafficked uteruses, and suffer harm to their professional status and reputations.

Views differ on the ethics and legalities of encouraging or accommodating donations, outside familial and analogous relationships, directed only to individually named or generically described recipients, as opposed to requiring donations to be distributed according to the policies of preferably publicly accountable agencies, governmental or otherwise, that receive transplantable organs for allocation. An advantage of directed donation is that it may induce donations by those unmotivated to incur the discomfort, inconvenience and costs of donation to unknown recipients. Expansion of the donor pool by individual-directed donations serves entrants on the waiting list for transplantation, if it removes candidates of higher priority than themselves, moving them up the list.

Disadvantages include social divisiveness, if donors are allowed to direct their donations toward, or against, members of populations identified by race, ethnicity, religion or other criteria of social characterization, which might amount to the private practice of public discrimination. An ethical and legal challenge for governmental and nongovernmental organ allocation agencies is whether they should accept charitable donations of organs that are subject to eligibility criteria for receipt that offend public values of nondiscrimination. Favoring some intended recipients, such as military veterans, can be seen as rewarding their valor, but also as disadvantaging others, such as those who were ineligible to join military forces, which historically meant disabled people and, in many countries, women.

A further concern is that the ability to attract directed donation from strangers might encourage and reward prospective recipients' competitive, aggressive public attention-seeking and self-promotion. Concerns have been raised, for instance, by sick patients or their family members using public news media and social media to publicize their

desperate solicitation of organ donations by showing intended recipients, such as children or parents of young children, as attractively, appealingly, and sympathetically as possible. Some find this emotionally exploitive and manipulative of possible donors, disruptive of equitably prioritized transplantation waiting lists, and discriminatory against less appealing candidates equally eligible for transplantation, noting that it creates an invidious “beauty contest” between potential recipients of organs.¹⁸ Others see the ethical need critically to question objections to private promotion of candidates, since competition for the scarce resource of transplantable organs pervades many organ allocation systems.¹⁹

A related issue is identification of recipients to donors and vice-versa. Identities are clearly mutually known in donations within families and friendship networks, and those who designate individual recipients know who they are, but recipients might not know the identities of their benefactors. Many public organ sharing agencies work on the principle of mutual anonymity between donors and recipients, to the extent that they will decline to handle a proposed designated donation unless they can allocate the organ according to their own priority criteria rather than the donors’ intentions. An ethical concern, which might be shared in law, is that a donor may subsequently ask an identified recipient to show gratitude by reciprocating the gift, including through payment, creating commerce *ex post facto*.

A donor’s less mercenary but not necessarily more benign expectation might be to create a relationship of friendship with the recipient and/or the recipient’s family. Uterus donation might evolve in an occasional reflection of surrogate motherhood, in which a woman previously unknown to a couple might provide them with the gestational

service in the hope of an ongoing relationship with the delivered child and its parents.²⁰ This hope or even expectation of a familial relationship with the child and its family may be uncomfortable for and unreciprocated by the parents, and confusing for the child as it matures. Prospective uterus donors to previously unknown recipients might be counseled against expecting continuing contact with recipients whose identities they come to learn, since uterus donation does not make them a family member of the child’s or of the parents’.

This brings to the forefront the questions, once payment in money or kind is excluded, of what might motivate a woman to donate her uterus for an unknown woman’s childbearing, and of by what criteria of ethics and law her donation might be assessed. Invasiveness of the nontherapeutic surgery to excise her uterus intact, that is, of a medically nonindicated hysterectomy, and possible psychological sequelae of implantation of the uterus in an unknown woman, raise ethical and legal concerns, for instance, of freely given, adequately informed consent, and of requirements of confidentiality. Such questions have been addressed in the UK by the Nuffield Council on Bioethics in a wide-ranging, rigorous, and instructive report.²¹

This observed that “Domestic legislation within the UK, EU [European Union] Directives and Council of Europe instruments²² all recognize, in various forms, the need for particular protection of living donors, especially as regards living organ donors. In the UK, the HTA [Human Tissue Authority] regulates all living organ donations, with the aim of ensuring that the consent provided by the living donor is fully informed and that there is no evidence of coercion, duress, or reward... Donors are only accepted after detailed medical and psychological assessment... Where a person is offering to

donate an organ to a stranger, rather than to a relative or friend, approval must first be sought from a panel of at least three members of the HTA.”²¹ This provides a procedure of independent, experienced, and disinterested review of live unrelated organ donors that might ensure the rights of women considering uterus donation to strangers, and neutralize any conflicting interests of research or clinical programs seeking the acclaim and rewards of new achievements in reproductive health.

Pervading the literature, doctrine, and traditional understanding of live organ donation, strongly reflected in codes of health professional ethics and in laws, are promotion of altruism and condemnation of providing or seeking material rewards that serve as incentives for donation. This approach requires scrutiny in practice, and self-critical reflection in ethical and legal analysis, where the purity of theory might be contaminated by the realities of practice. Although motivated in principle by altruism, donors are almost invariably considered entitled to reimbursement of their expenses and reasonable compensation for the opportunities they lost in the cause of donation, such as recovery of lost wages and earning opportunities. Accordingly, while direct money payment in exchange for organ donation is ethically condemned and often legally prohibited, money not uncommonly passes from or on behalf of recipients of organs to those who donate them outside of their family or friendship networks. Such payments can cover donors’ disability, discomfort, and inconvenience in preparation for and recovery from donation, and seem generous in the prevailing economic climate. The Nuffield Council report observed that “attitudes to the role of payment in the donation of bodily material differ significantly around the world”²¹

This bland observation masks a conflict that continues to rage in ethics between opposing worldviews. One denies “ethical relativism”, asserting absolute ethical values, and condemning departure from uncompromised ethical norms as corrosive of the function of ethics to distinguish between right and wrong conduct and motivations. Much of the modern human rights movement is founded on the conviction that some treatments of human beings are absolute offences against human dignity and human rights, requiring universal prohibition. Some religions that aspire to universal adherence identify their teachings with ethical orthodoxy and reject ethical relativism as an unprincipled, heretical “anything goes” philosophy that warrants condemnation, ostracism, and punishment.

Opposing this view is condemnation of “ethical imperialism” through which adherents to one vision of ethical conduct seek to impose their vision on others of different persuasion, and to compel obedience to their own judgment of right and wrong. This is a criticism sometimes made against modern bioethics, which is a product of western culture and sophisticated medical technologies that can initiate and prolong human life by postponing death. Bioethics’ preoccupation with individual autonomy may appear at variance with lives lived within family and communal relationships in which autonomous decision making is seen as an impertinence, since decisions, including regarding individuals’ medical care, are familial, relational, and communal, to serve collective interests as understood by heads of families and community elders and leaders.

A dilemma of ethical absolutism is exposed in support of the principle expressed in the Universal Declaration of Human Rights, given legal force in Article 18(1) of the United Nations’ sponsored International Covenant

on Civil and Political Rights, that without exception everyone “shall have the right to freedom of thought, conscience, and religion”, including “freedom to adopt a religion or belief of his choice”. More than one of the world’s prominent religions or religious denominations claim sole possession of absolute truths denial of or deviation from which constitutes heresy. Abandonment or renunciation in whole or in part of this one true faith, apostasy, merits the most severe of spiritual and temporal punishments. Individuals once of the given faith are not free without penalty to profess a different, or no, faith. An equivalent dilemma of adherence to ethical relativism is the extent of its accommodation or tolerance of religious and ethical intolerance.

Prohibition of paid uterus donation lies at the center of the contest between ethical absolutism and rejection of ethical imperialism, justifying the Nuffield Council observing that “attitudes to the role of payment...differ significantly around the world”. Objection to paid organ donation, which is particularly strong in Europe, is not just to the commodification of the human body, in violation of the Kantian imperative not to treat people only as objects, but that the wealthy might exploit the poor. They might buy themselves or their family members childbearing capacity by inducing disadvantaged women to surrender their own, endangering their health and that of others such as disabled family-members who depend on their availability and energy. A related concern is that payments may be sought by relatives able to persuade their vulnerable family members, perhaps dependent widows or others past their childbearing years, to become donors.

As against prohibition of payment, however, the Nuffield Council observed that “Iran is the one country in the world that explicitly renders reward for organs legal. Although Iran is widely described as promoting a *legal*

market in organs, the permitted payment is in fact described as a *social gift*, administered by a nongovernment agency”.²⁰ Between the alternative of a prohibited market, which is liable to be evaded with close to impunity by unscrupulous traffickers, or an open market in which vulnerable women are at risk of exploitation and injury, Iran offers a model that incorporates a regulated market. An intermediary governmental or nongovernmental agency that sets payment rates and unlinks organ donors from recipients might allocate donations according to potential recipients’ needs rather than their means to pay, and provide, as in Iran, for donors’ free life-long health insurance.²¹

By these principles, it is feasible that an ethical system of paying uterus donors fees exceeding their expenses of donation might be established. Payable fees in a transparent regulated market might be set at a rate that would not tempt economically disadvantaged women to reckless donation, but address the apparent inequity that, while healthcare professionals conducting a uterus recovery procedure, professionals transplanting the organ into the recipient in a procedure taking about 5 hours,¹² attendant nursing and related personnel, the healthcare facility accommodating the procedure, and, for instance, drug companies supplying necessary provisions are all receiving payments, the organ donor herself is required to be altruistic by prohibition from receiving any payment. Indeed, if her claim for reimbursement of expenses she incurs in preparing for and undertaking donation are too strictly audited, the donor may financially subsidize the transplantation.

DECEASED (CADAVERIC) DONATION

Deceased donors are people who, while living, legally consented to their organs being recovered after their death for transplantation,

perhaps among other options for use. Several legal systems, such as in countries with advanced medical cultures and technologies, accommodate advance medical directives that people make in anticipation of their disability and death to plan what happens when these occur. Alternatively, they are people who had given no such consent or other direction for management or disposal of their remains but whose family members legally consent to organ recovery because prior to death the deceased had expressed no objection to posthumous recovery of their organs for transplantation.

Objection to posthumous removal of organs might not have been explicit, however, because, for instance, deceased persons who held firm religious beliefs in resurrection might be expected to want to retain their organs. The physiology of anticipated resurrection has not been specified, but if it is considered to be not just spiritual but also physical, it may be presumed that adherents to this belief would not want their organs removed. In the absence of the deceased's explicit or implicit objection, however, family members close to the deceased are often empowered to provide legal consent to organ recovery. In a strict sense, family members who give consent are the donors, but for medical assessment and processing of organs, for instance to determine suitability of organs for transplantation in light of the deceased persons' medical histories, it is convenient to refer to the deceased as the donors.

Death is usually declared by healthcare professionals as a medical condition that determines further events, such as burial or cremation and prior recovery of body materials, for instance for post-mortem examination, or transplantation. Death is also a legal status, conditioning inheritance such as by distribution of deceased persons' estates. Historically, death was signified by

cessation of cardiac function or heartbeat, but with development of artificial respiration that sustains cardiac function, other criteria have become available, particularly to monitor neurological activity, that is, brain function. Legal systems differ on how death may be determined.

Determination of brain death and cardiac cessation depends on sensitivity of tests, since brain, cardiac, or pulmonary activity might be too suppressed to be detected by some monitors. Cessation of cardiac and/or neurological activity as a determinant of death may rely on medical diagnosis, but death may be also be seen as a prognosis, perhaps indicating the (in)appropriateness of cardiac resuscitation initiatives. Some laws specify that cardiac death requires "permanent cessation" of cardiac activity. By whichever criterion it is determined, death is also a prognosis of tissue deterioration, more important when organ recovery for transplantation is proposed. Recovery has to be undertaken promptly upon confirmation of death and assurance of ethically appropriate lawful consent, given before death by the deceased or after death by those legally entitled to provide consent.

A gynecological surgeon removing a cadaveric uterus for transplantation must obtain assurance of the donor's death from a professional legally entitled to certify death, but does not have to address ethical issues of the donor's management prior to determination of death, although whether the dying patient's care was managed according to the apparent best interests of the patient or to maximize organ viability for transplantation might be contentious. It is often considered that organ viability for transplantation is best preserved by retaining the organ in the body of the deceased transfused with its own blood, which is achieved by artificially maintaining cardiac

function after death has been confirmed by a brain death determination. Removing organs for transplantation from heart-beating donors historically raised alarms, and the matter is not beyond contention today, but professional protocols for the practice have been published and publicly tolerated, and surgeons legally entitled to undertake removal may decide for themselves whether to proceed.

The Swedish team-members who reported their success in February, 2015 considered the relative merits of live and cadaveric donation. They noted that “uterine donation from a deceased donor would obviously substantially reduce the overall risk and complexity of the surgical procedure. In the uterus transplantation that was done in Turkey in 2011, the uterus was from a heart-beating, braindead 22-year-old female donor who had never been pregnant. Naturally, the young age of that uterus and its vasculature would offer a benefit but this has to be balanced against the advantage of a uterine graft that has proved its functionality in terms of normal pregnancies. Moreover, the live donor concept allows for meticulous diagnostic workup of the uterine graft to exclude pathologies that could interfere with fertility potential, such as adenomyosis and endometrial polyps.”⁸

A subsequent commentary, taking account of three live births that were recorded after uterus transplantation and that “wombs for transplantation can be and have been obtained from both the living and the deceased,” addressed whether cadaveric donation might be morally preferable.²³ It noted that “unlike deceased donation, living donation necessarily causes some physical harm to the donor and includes a small but not insignificant risk of long-term morbidity and mortality, as well as generating concerns regarding donor consent and the possibility

of regret”. The commentary added that “teams based in the US, UK, and Turkey suggest that... longer lengths of vasculature can be obtained from the deceased, lessening the chance of complications and rejection in recipients.”²³ The commentator, whose research is in philosophy and politics, concluded that “should it be the case that there is both no shortage of deceased donor uteruses and that the use of living donors is no more likely (or only slightly more likely) to prove successful, those who hold that living donation requires a favorable harm-benefit ratio may claim with good reason that only deceased donors should be used.”²³

However, whether there is or would be “no shortage of deceased donor uteruses” has been doubted. Some causes of death preclude transplantation, uterine cancer being an obvious example. It has been observed in the UK that “only a small percentage of people die in circumstances that enable them to become donors (most organs are harvested from patients in intensive care units who are being ventilated)”²⁴ It is a matter of local law whether such ventilated patients can be considered dead. The Swedish team contrasted their live donation with the 2011 instance in Turkey involving “a heart-beating, brain-dead donor,”⁸ confirming that the body’s mechanically maintained heartbeat was not incompatible with certification of the body being dead, but this would not be accepted in legal systems, medical cultures, and religious traditions that do not accommodate the concept of brain death and accordingly prohibit removal of organs for transplantation from heartbeating bodies. Replacing the ancient fear of premature determination of death and burial while alive is fear of premature procurement of transplantable organs.²⁵

A further reason why uteruses might not be recovered from cadavers, or be of use

if removed, is that when consent has been assured for removal of multiple organs for transplantation, priority is likely to favor removal and preparation for transmission of vital organs, on which the survival of seriously endangered patients depends, rather than on recovery of a uterus. It would be different, of course, if the uterus is the only organ that the deceased or her family member approved to be recovered. Delay in postmortem recovery, from whatever cause, might prejudice or deny viability of a uterus for transplantation, without necessarily indicating that women's reproductive health interests do not rank highly as a medical priority.

UTERUS RECIPIENTS

The successful Swedish team presented their clinical criteria and procedures for managing their uterus recipient in considerable detail that generated an amplifying correspondence,²⁶ including their response.²⁷ Unlike organs transplanted to prolong life, a uterus would be transplanted for transitory employment. As the team explained, "the graft is not intended for lifelong use. The uterus can be removed after one or two babies have been born, which would reduce the long-term side effects caused by the immunosuppressive drugs."⁸ One of the first transplant recipients in the Swedish study was reported in June, 2016 to be pregnant again,²⁸ postponing what otherwise would be immediate postpartum hysterectomy until after delivery of the second child.

Accordingly, the sequence of invasive procedures to which a uterus recipient agrees²⁹ would be:

1. Removal of a non-functional uterus, if she has one
2. Ovum recovery for IVF to establish fertility (with sperm from partner or donor), and embryo cryopreservation
3. Uterine graft allotransplantation, in which the donor's uterine arteries are anastomosed with the recipient's external iliac arteries
4. Recipient begins immunosuppressive regimens followed by a year-long follow-up to evaluate her response and to ensure graft viability
5. Recipient undergoes transfer of thawed embryo cryopreserved from IVF and, if implantation is successful, the ensuing pregnancy is closely followed up under a compatible antirejection regimen
6. Recipient undergoes planned delivery by cesarean section
7. Embryo transfer can be repeated 1 year after delivery, if desired, repeating (5 and 6) above
8. Recipient undergoes hysterectomy to spare her life-long exposure to immunosuppression.

The Swedish team explained that IVF before transplantation ensured fertility and was desirable to create embryos for subsequent transfer to achieve pregnancy, since IVF after transplantation might be more difficult, with increased risk of bleeding at ovum recovery, and of pelvic infection in an immunosuppressed patient. Each step in the sequence, from determining whether to propose live donation from a family member, or from an identified or anonymous live donor, or cadaveric donation, presents ethical concerns. For instance, family members eligible to donate may feel the pressure of being expected by others in the family to offer donation, and feel guilty or liable to be blamed for declining and a loved relative remaining childless. When cadaveric donation is available, it would probably be anonymous, but the prospective recipient might want to know something about the donor, and circumstances of her death. Death from unpreventable brain hemorrhage or

head trauma in a traffic accident might be received differently, for instance, from death by suicide or domestic violence. What to tell of what is known might present a challenge where the ethic of truth telling is highly esteemed.

Beyond ethical concerns specific to uterus transplantation itself are the ethical concerns surrounding IVF, such as planned or incidental wastage of embryos created *in vitro*, criteria and procedures for selection of embryos to transfer, particularly when none created appears ideal, and transfer of two or more embryos in recipients of advanced maternal age, with an option of offering or performing fetal reduction if multiple pregnancy presents unacceptable risks to recipients and/or their fetuses or subsequently born children. Embryo selection for transfer based on pre-implantation genetic testing should be in consultation with intended recipients, but raises sensitive ethical issues such as sex selection and selection involving disability. Further, disclosure might ethically be required of limits of professional understanding of the significance of test results, such as mosaicism and segmental imbalances. These concerns fit into the wider framework of practicing as an ethical professional gynecologist, however, determining for instance which patients might be offered uterus transplantation. This presents the ethical challenge of whether to distinguish between those affected by primary or by secondary infertility, and those able to offer their children well ordered, adequately resourced upbringing, and, if procedures become publicly funded, those with feasible access to uterus transplantation but who are less equipped to provide for their children's material, or emotional, needs.

One prevailing set of ethical concerns promises to be relieved as uterus transplantation passes from constituting clinical research to become standard if exceptional

therapy, but until that transition, procedures will be subject to ethical principles governing research with human subjects. Ethical and legal criteria of freely given informed consent, and for instance of confidentiality, are comparable to those governing routine therapies, but there are more stringent criteria concerning research, such as prior submission of research protocols to independent research ethics scrutiny, and regarding who may be recruited into research studies. A requirement of gender equality is obviously inapplicable, but establishing a favorable benefit-to-risk ratio is particularly challenging when innovative treatments are proposed, here involving repeated major abdominal surgery, and when alternative options for recruits are legally restricted, as surrogate gestation is in some countries, or, like adoption, unavailable or unacceptable to those who want genetic lineage with their children to perpetuate family heritage. The benefit-to-risk ratio is speculative to calculate, because "currently, we have no empirical evidence comparing the difference in quality of life between recipients of uterus transplantation versus women with UFI employing surrogacy or adoption. We do not know yet the psychological and societal factors that would influence uterus transplantation as we do in [other] transplantation... The exit plans for uterus transplantation are also more ethically and clinically complicated... given the potential addition of the fetus gestating inside the transplanted uterus. The decision to increase immunosuppressive therapy versus remove the uterus if rejection occurs is certainly made more complex if the recipient is pregnant."⁷

A further contrast between the ethics of research and of therapy is that before research with humans can be undertaken, prior research must have been conducted on appropriate animal models, which for uterus

transplantation includes nonhuman primates. The ethics of animal experimentation are not necessarily less complex than those of human studies, and while disposal of rodent models after dissection might be considered a justifiable sacrifice, it might not be offensively “speciesist,” *pace* the philosopher Peter Singer,³⁰ to claim that primates subjected to invasive research require greater respect and protection, because they are more closely related to humans. The background training of surgeons must, of course, be adequate as a condition of their licensure and appointment to clinical practice, but they do not have to submit to independent review of their credentials and experience before they undertake each procedure on patients in the same way required of researchers in a career of sequential human studies.

In both research and eventual therapy, transplant recipients must ethically be informed, and adequately understand, that the experience of a resulting pregnancy will not be the equivalent of that experienced by women pregnant in their own uteruses. Each pregnancy generates unique experiences for women, although there are health effects that are common, but not uniform, such as morning sickness and swollen ankles. The sensations women experience when pregnant through a transplanted uterus are distinctive. It has been explained that “given that it is not feasible to anastomose the pelvic nerves during uterus transplantation, many of the normal sensations of pregnancy and labor may be perceived differently by the recipient... Researchers must be careful to inform subjects that because the nerves will be severed, they will not experience the complete experience of pregnancy. However, they will be visibly pregnant, emotionally pregnant and seen as pregnant by society—important considerations as they are the ultimate goals of uterus transplantation.”⁷

These considerations of recipients’ profound satisfaction in gestation and parenthood of their genetic offspring provide the ethically required favorable benefit-to-risk ratio in uterus transplantation research that has justified its approval.

In uterus transplantation research and anticipating when the procedure is adopted as a surgical means to redress UFI, gynecologists, counselors, and recipients themselves ethically must consider risks to the fetus the procedure is intended to bring through gestation to live birth. It has been observed that “the fetus would be subjected to immunosuppressive therapy which may have the potential for teratogenesis as well as other adverse effects such a preterm delivery. If an acute vascular thrombosis were to occur... fetal development could be negatively impacted by hypoxia or stillbirth could result.”⁷ Reassurance may be found in the reported normal pregnancy and good health status of the child born, slightly prematurely, in the breakthrough Swedish research. Where women are ethically respected as entitled to make their own reproductive choices, such as to initiate pregnancies that carry the risks to fetuses of uterus transplantation or, for instance, when infected with the human immunodeficiency virus (HIV), gynecologists and others are ethically entitled to provide them with the evolving resources of medical science to minimize risks and maximize benefits.

LEGAL CONCERNS REQUIRING ETHICAL RESPONSES

It has been seen above that, in addition to a range of ethical concerns, uterus transplantation involves central legal concerns such as freely given adequately informed consent, prohibition or limits of commercial payment for donation and, for instance, definitions of death. Wider legal issues

are also engaged, however, from concerns about the status of an excised uterus prior to implantation in a recipient, to public funding of uterus transplantation research and therapy, and respect for the human rights of unorthodox recipients. Gynecologists discharging clinical, supervisory, and/or administrative responsibilities might be required to prepare ethical responses that address legal aspects of their functions, or to consult with others, including but not necessarily or not only lawyers, in fashioning policy responses. Law is often described as a minimum ethic, in that everyone should act within the law, but ethical conduct frequently requires more than a legal justification. That is—it is not a satisfactory ethical justification of conduct that it is lawful. The exercise of a legal right or choice can be unethical if the right is abused, in violation of ethical principles such as beneficence, or justice.

It is now widely accepted that, outside the body, human tissues and organs might be treated as property. With legal abolition of slavery, living persons and the tissues, fluids and organs that constitute them are not treated as property, but once outside the body, such materials might in law have the status of property if they have value, which is usually derived from their utility.³¹ On introduction of uterus transplantation, an excised uterus might have value, for research and potentially for therapeutic implantation, and accordingly may be treated as property, even though many legal systems prohibit or limit its transfer for payment. Indeed, the legal control of its exchange for payment is consistent with its status as legal property.³²

The question of ethical concern is to whom a removed uterus may be considered to belong. It is not property inside the donor or cadaver, nor when implanted in a recipient, but questions of ownership and lawful possession arise when it is in transit between.

The living donor might have abandoned her uterus on removal, because she does not require its return,³³ but it does not belong to the recipient until implantation, when, being part of her, it is no longer property. Court decisions treat donated research materials as the property of the institutions that hold them, meaning universities, hospitals or clinics rather than any of their staff members. It is open to the facility that holds the uterus in transit to treat it as its own, but more ethically appropriate to consider itself trustee of a living donor's property for transfer to the recipient she designated, or to a suitable undesignated recipient. Recovery from dead bodies makes organs the property of those primarily in charge of recovery or of their employers, unless the organs are governed by an enforceable advance directive or testamentary gift, that is, by a will. Disposal of the uterus on removal after its use for gestation, if it cannot be implanted in a subsequent recipient, or if it proves unsuitable for implantation, is less of a concern. When it no longer has any value, it will be disposed of as the equivalent of pathological waste, by incineration or other means, governed more by public health law than by property law.

The funding of uterus transplantation as research, and potentially as therapy, is a policy decision, based among other factors on economic and ethical considerations, to be implemented by legal means. Decisions lie with medical research funding agencies, whether governmental, institutional or, for instance, private, such as charitable foundations, and for therapeutic initiatives, with health service providers, such as governmental in the public sector and health service insurance in the private sector. It may be presumed that costs would exceed the means of all but few prospective recipients and/or their families. For instance, when, in 2015, a UK hospital in London received ethical

approval for clinical trials of ten uterus transplants from brain-dead women, it was necessary to raise half a million pounds to proceed.¹¹ Cadaveric organ recovery is less expensive than from live donors, and in the UK pregnant recipients' maternity care is covered by the regular governmental health service, and would not be a research cost. A member of the Swedish trial who joined the first successful US team at Baylor University Medical Center estimated the cost at around \$200,000 to \$250,000.³⁴ Accordingly, without regard to other ethical considerations, the costs associated with uterus transplantation, including a 5-hour surgical procedure to implant a uterus in the recipient, and an equally long procedure completing radical hysterectomy for a live donor, raise difficult ethical issues of resource allocation for research teams, clinicians, and funding agencies supporting each. Nevertheless, when several competing ethical arguments for and against public funding are weighed against each other, public funding might be considered ethical.³⁵

A number of additional ethical responses are required to conform to provisions of nondiscrimination and human rights laws. Whether or not UFI is considered a disease, it is a disability, and laws increasingly prohibit discrimination against persons with disabilities. This is an ethical factor, for instance, in research and health service funding decisions, and in selection and priority setting among candidates for receipt of organs. Nondiscrimination considerations affecting single women, whether never married, divorced or widowed, and those in lesbian relationships, also require ethical responses, not least because courts in several countries have condemned gynecologists who denied reproductive health services to such women. A projection of this concern may arise regarding uterus implantation into

male-to-female transgender patients, and perhaps in time, into men. This takes ethical responses beyond the scope of this chapter, into the ethics, for instance, of conscientious objection.

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Section 3

The Intersection of Health Policy and Clinical Practice

CHAPTERS

Main Challenges in the Professional Practice of Obstetricians and Gynecologists in Sexual and Reproductive Health Services

Leonel Briozzo

Conscientious Objection and the Duty to Refer

Bernard M Dickens

Current Ethical Challenges Facing the Obstetrician-Gynecologist: Conflict of Interest

Ralph W Hale

Criminalization of Medical Errors

Sanjay Gupte



Main Challenges in the Professional Practice of Obstetricians and Gynecologists in Sexual and Reproductive Health Services

Leonel Briozzo

INTRODUCTION

Sexual and reproductive health issues of women and men constitute an essential topic in the policy agendas of governments and countries around the world. Women suffer the burden of high morbidity and mortality rates given the vulnerabilities that add up in the reproductive process and sexual relationships. This burden, already higher in women, increases even more the social inequality affecting women in many countries, regions, and communities, in particular, in the developing world. Yet, this inadmissibly high burden may be prevented to a large extent, the most paradigmatic example being the differences in terms of maternal mortality, the greater health indicator that reflects inequality with regard to the role and value of women in the different countries and at the domestic level, in the different social sectors. Women's sexual and reproductive health is usually compromised as a result of the violation of basic human rights in women, rather than due to the lack of medical knowledge. These violations also have an impact on the ethic and professional responsibilities of health professionals who deal with the care of women.¹

SEXUAL AND REPRODUCTIVE RIGHTS

Sexual and reproductive rights were systematized for the first time within the context

of the human rights at the International Conference on Population and Development (ICPD) in Cairo, Egypt, in 1994.

In short, sexual and reproductive rights are:

- The right to a risk-free motherhood
- The right of women and couples to control fertility
- The right to a sexual life free of violence, disease, and unwanted pregnancy
- The right to interrupt pregnancy in the cases provided for by law and, in the event abortion is not provided, the right to professional counseling and support for women undergoing unwanted pregnancies
- Universal access sexual health and reproductive services
- The right to access safe information in connection with the aforementioned rights.

Sexual and reproductive rights appear as a consistent reaction to discrimination against women, which constitutes a human development problem, since women are essential for the social and economic stability and progress across all societies. The potential contributions of women are usually prevented by limitations on their human rights, including the lack of access to information and safe and adequate care. In this way, sexual and reproductive rights embody a global guide for social organizations that

defend and promote women's health and life, and simultaneously inspire public policies developed by countries around the world that provide guidelines for health professionals' practice. In particular, these guidelines are of paramount importance to gynecologists and obstetricians, since they have a great impact on women.

Sexual and reproductive rights are vital for all women, although their defense and promotion are particularly important in women who suffer some kind of violation. The following problems, among others, may be regarded as the causes that constitute obstacles for the development of these rights:

- The impact of poverty and social exclusion
- The impact of discrimination against girls and adolescents
- Aspects in connection with the ethnic-racial condition, the so-called indigenous groups and black peoples and Afro-descendants, are especially vulnerable
- Any kind of disability
- Belonging to sexual minorities
- Migrant populations and areas of conflict.

In response to these violations, the bio-ethical principle of equity or justice implies the need to develop actions, both individually and at the public policy level, in the form of practices and policies that protect and promote the rights, interests, and welfare of vulnerable populations. Governments across the world have promoted different mechanisms to ensure sexual and reproductive rights. These services rely on professional multidisciplinary teams where obstetricians interact with midwives, nurses, general practitioners, pediatricians and neonatologists, experts in mental health, among others, but always, with the key participation and lead of obstetricians and gynecologists.

Within this framework, sexual and reproductive rights deal with relevant aspects that have to do with personal decisions

of individuals that affect the individual and collective health and happiness warrant priority for public policy. To this end, the participation of obstetricians and gynecologists in the sexual and reproductive rights services is a vital aspect of the professional practice.

PROFESSIONAL VALUES AND MEDICAL PROFESSIONALISM

There is an evident inequality between women who seek medical care and physicians who provide these healthcare services, in terms of power. This difference arises as a consequence of cultural and economical differences, as well as from differences that have to do with differences in knowledge and experience between doctors and their patients. Physicians have a significant social responsibility and play a prominent role in society on the basis of their knowledge and skills. This status provides the means to influence the social and health policies that enable them by pointing out inequalities in the sexual and reproductive healthcare of women and fighting for a higher general status for women. To that end, health professionals in general, and obstetricians and gynecologists in particular, need to base their practice on the values that compose medical professionalism.

A key component of professionalism is defined as an individual's quality or characteristic and what makes him or her valuable. Certain values are socially recognized, as is the case of rules for coexistence existing in a given place and time. A few of them are freedom, justice, responsibility, solidarity, courage, and honor, among others. For the medical profession in particular, the values are vocation, discipline, competence, and commitment.²

- Vocation may be defined as the overriding importance of professional social role over economical benefit.

- Discipline—defined as the subordination of professionals to the rules established by the group/association. In the case of obstetricians and gynecologists for instance, to ascribe to the FIGO Code of Ethics.
- Competency defines the technical quality and is composed by three components—(1) knowledge, (2) skills, and (3) attitudes in terms of interpersonal relations. The main value of competency is knowledge and the capability to apply it.
- Commitment is the ability to get involved in the patient's problem beyond the considerations of the professional himself. In this way, it has to do with morality in terms of honestly using knowledge in the professional practice.

From this perspective, in order to act on the basis of medical professionalism, physicians need to apply these values and principles in their professional practice. The medical profession is a social group with specific credentials and a compromise with concrete behaviors that necessarily need to be controlled and renewed during the entire professional life. Professional ethics is the means to attain coherence between the commitment with social development and the right professional practice. From the profession's viewpoint, respect and the promotion of human rights that ensure everybody's full exercise of their conscious capacity embody the main conditions to build and preserve a harmonious relationship with society.

BIOETHICAL PRINCIPLES AND PROFESSIONAL PRACTICE

The human right to the highest standards of attainable health and the benefits of scientific progress creates extraordinary obligations by the medical community across the world. Bioethics, among other aims, seeks to systematize the conditions for the right thing to

do honest, compassionate, and committed actions by professionals.

Obstetricians and gynecologists have distinctive obligations toward women's health, arising from ethical considerations. The principle of beneficence creates the obligation to always act in the benefit of the patient, and its modern interpretation implies that the woman herself needs to consciously decide what is good for her. The principle of nonmaleficence principle implies the need to avoid causation of harm, it is often better to refrain from doing than going and causing harm.

The principles of autonomy (which includes preservation of bodily integrity) and justice add to these two Hippocratic principles. With regard to the principle of autonomy, it is key to recognize the freedom of conscience, as well as women's liberty and safety as human beings. To the profession, promoting autonomy implies understanding and fostering independence and the decision power of individuals and communities. This independence and power of individuals and communities need to be defended from any other power, including, needless to say, the so-called "medical power" characterized by the power held by physicians, which was conferred to them by the nonautonomous and authoritative "paternalistic" medical model.³ Last, the principle of justice implies the need to always act according to needs and to provide more care to those who need it the most, based on the compassionate sense of medicine that aims at justice in terms of the real possibilities of accessing health services.

MAIN CHALLENGES IN OBSTETRICIANS' AND GYNECOLOGISTS' PRACTICE OF SEXUAL AND REPRODUCTIVE RIGHTS

There are challenges for obstetrician-gynecologists in respecting and implementing

sexual and reproductive rights services. These challenges include:

- Professional practices that reassert the medical paternalistic model.
- The lack of promotion of the principle of autonomy and failure to empower women as the key actors who are at the core of the doctor-user relationship.
- Institutionalized regulatory organizations of profession (medical associations, universities, etc.) are not concerned about providing the right training of human resources in these issues, and there is no supervision of the professional practice on the different health areas.
- The lack of confidentiality in healthcare services, especially in the case of women's multiple vulnerabilities, cases of girls and adolescents, racial minorities and others. The lack of confidentiality is particularly serious for women in risk situations related to pregnancy, and many of them, unless confidentiality is ensured, would rather risk their life instead of dully seeking counseling services as is the case of unsafe abortion.
- The lack of professional training or continuing medical education still prevail with regard to sexual and reproductive health and the lessons learned to improve it.
- The prioritization areas of healthcare that require high technology or demand specialization.
- Difficulties in accepting the multidisciplinary nature of other disciplines such as sociology, psychology, and law.
- Fear of being exposed to publicity that stigmatizes health and sexual and reproductive rights issues, in spite of our having a perfectly defined position and behavior.

If we understand that society confers a certain value to a certain profession, or removes it from the same profession, we need to agree that the absence of an explicit vision and a mission that defends and promotes

sexual and reproductive rights as human rights is a significant challenge. On the one hand, lack of a vision and mission risks the bases of professionalism and its value; and on the other hand, it places obstacles to attain the human right to health by women and communities.

PERSPECTIVES FOR PROFESSIONAL ACTIONS IN THE SEXUAL AND REPRODUCTIVE HEALTH SERVICES

The topic is relevant besides, as the society of Obstetricians and Gynaecologists of Canada (SOGC)³ states—“health professionals are in an exceptional position to introduce changes in the field of sexual and reproductive rights. They have the medical competency, social position, credibility, and commitment to improve health, and they also have contact and reach the wider community. They may influence decision makers and policy makers at the global, national, and international level.”

As a matter of fact, several actions may be developed to promote the independence of women and communities geared to empowering women, so that they can make informed, responsible, and voluntary decisions in connection with their health.⁴ As the SOGC³ states, empowering women means: “ensuring women and men have equal access to income, education, healthcare and other resources and that they can make free and informed decisions on their lives in a safe environment”, and it further states that “the importance of acknowledging this empowerment of women in all programs and politics related with women's health is never over-emphasized”.

The tools medical professionals may use in the promotion and development of sexual and reproductive rights are primarily basing their practice on professional values, the

evidence arising from or and the institutional definitions they may attain regarding sexual and reproductive rights. Doctors play a paradigmatic role as part of a team that care for and supports women. The challenge lies in seeking training on the defense and promotion of sexual and reproductive rights to develop a kind of practice we were never prepared for in medical school.

The International Federation of Gynecology and Obstetrics (FIGO)⁵ has made relevant and important recommendations in connection with the doctor-patient relationship, pertaining to the professional responsibilities of obstetricians and gynecologists:

- To support a decision-making process that is free from prejudice and coercion and allows women to make informed decisions regarding their sexual and reproductive health. This includes the need to act toward obtaining the informed consent or disagreement of users, based on providing patients with adequate information on the nature, implications of treatment, options, and results in connection with their choices. In this way, health professionals provide women with the chance of considering and assessing their treatment options within the context of their own circumstances and culture.
- To ensure that confidentiality shall prevent privileged information and documents to be shared verbally or in any other way, except when required by law or when users wish it to happen.
- To respect the nondiscrimination principle to ensure that all women are treated with respect, regardless of their age, marital status, ethnicity, political affiliation, race, religion, economical status, disability, or any other condition. The opinion of women should be respected, rather than that of their couple of family.
- To ensure that adolescents are treated without discrimination according to their capacity instead of their biological age and that they receive help to make free and informed decisions on their sexual and reproductive rights.

The training of professionals is a priority and the inclusion of sexual and reproductive rights and communication strategies in the human rights syllabus is of the essence. However, in Leaning's words⁶ apart from institutional initiatives "there might be no better place to start raising awareness on human rights and human dignity than the small doctor-patient world". Thus, the daily tutoring of health professionals who are committed to sexual and reproductive rights is a fundamental part in the training of coming generations.

The FIGO's guidance is very important for promoting sexual and reproductive rights and health:

- To advocate for women's right to the information and education that allows them to decide when to have children, as per the autonomy ethical principle and the human right to decide whether they want children and when they want to have them.
- To advocate for women's right to make decisions on matters related to their sexual relationships as a natural part of their lives, collaborating with their enjoying a free and safe initiation of their sexual life.
- To advocate for the required resources and services, so that women who seek a better sexual and reproductive health ensure their right to attain the highest health standard of sexual and reproductive health and the ability to benefit from scientific progress.
- To inform communities on the reality of sexual and reproductive rights and health to foster a wide and respectful dialog,

based on the best evidence, to influence the medical practices, policies, and the law.

Addressing the complex and dynamic field of sexual and reproductive rights and health from the professional perspective implies multiple challenges. Medicine, ethics, and law come together in this field¹ and this is a field that implies theoretical knowledge, practical skills, and committed attitudes. However, this field is usually subvalued in the professional arena.

COMMITMENT TO PATIENTS: THE KEY FOR MEDICAL PROFESSIONALISM IN OBSTETRICS AND GYNECOLOGY

As it was stated before, the value of committing to the patients' decisions is crucial for practicing according to medical professionalism in general, and in particular, it is important in aspects in connection with sexual and reproductive health. There are, however, exceptional occasions when health professionals also have the right to conscientious objection. This occurs when the patient's decisions are against the professional's personal beliefs based on religious or philosophical well-founded reasons. The case of abortion for nonmedical reason is may be the most paradigmatic example.

However, in spite of not being able to accommodate the patient's decision, in the case of conscientious objection, the physician is not acting against the patient's interest and medical ethics. When genuine, conscientious objection is part of the professional practice of a physician who is committed to patients, it should not create obstacles to access to the healthcare system. Referral of the patient becomes a professional responsibility, even if referral disturbs the physician's conscience. Unlike this case, the pseudoconscientious objection and the objection arising from

convenience and civil disobedience are anti-ethical attitudes.

Based on the above, the main contradiction lies between commitment and lack of commitment, rather than between objection and nonobjection. The defense and promotion of autonomy are part of the conscious commitment. Genuine conscientious objection accompanies this vision. Contrarily, lack of conscientious commitment is the real anti-ethical attitude, since this attitude subdues autonomy by aiming to impose the paternalistic model and even failing to provide aid. Personal conveniences, lack of interest dis-involvement and civil disobedience may hide behind conscientious objection, and this is the real problem the profession must face. In short, professionals should never impose our conceptions on patients. On the contrary, regardless of whether or not we agree with the decisions of our patients, our duty is to help decide in the most responsible, informed, and freeway possible. Thus, the development of awareness through the decisions of patients is one of the most important objectives of the medical profession. The confidence of society in the medical profession depends, to a large extent, on the commitment of professionals to the decisions of patients.

CONCLUSION

Sexual and reproductive rights are keys for obstetricians' and gynecologists' professional practice around the world. Learning about them, defending them, and promoting them are an obligation of the daily practice of the profession. Health professionals individually and as a group need must aim at promoting sexual and reproductive rights among the most vulnerable specific populations. Confidentiality of healthcare services is crucial to improve the doctor-patient relationship and to promote faithfulness among users of the health system. Professional secrecy that

ensures confidentiality constitutes a permanent ethical obligation of obstetricians and gynecologists. The commitment with the patient's decision may often result in health professionals facing a dilemma. However, overrunning the conscious decisions of women is never justifiable; the approach must always be a compassionate and committed one. Beyond the fact that conscientious objection is a reality, the main obligations is toward the life, health, and happiness of the patients who trust their health to physicians and the entire professional team at the time of consultation.

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Conscientious Objection and the Duty to Refer

Bernard M Dickens

INTRODUCTION

Conscientious objection has a long history opposing, on religious grounds, conscription into military service, and in healthcare since the late 19th century in parents opposing mandatory vaccination of their children, but objection acquired impetus after the 1960s when medical practitioners refused participation in services requested under increasingly widespread liberalized abortion laws. Some acted on their own initiative when patients took advantage of their newly recognized rights to request lawful termination of unwanted pregnancies, and others joined efforts orchestrated by religious and other organizations to resist requests for access to services. The conflict between patients' requests for lawful abortion and medical service practitioners' conscientious objections to participation might be resolved through practitioners' ethical duties to refer patients to nonobjecting practitioners, as required by many codes of medical ethics and laws. However, some practitioners claim that complicity in others' wrongs makes them as culpable as they would be for committing such wrongs themselves, and so invoke conscientious objection both to direct participation and to referring their patients to others for care.

Attention is therefore required to ethical principles underlying rights of conscience

to object for participation in lawful medical procedures, and also to referral of patients to nonobjecting colleagues.¹ In principle, conscientious objection may be made to participation in several lawful medical procedures, particularly regarding means of medically assisted control and promotion of fertility, including counseling or advising on means, prescribing related products and conducting related procedures. For convenience, however, the primary focus here is on abortion procedures, because they serve as reliable representative procedures that attract conscientious objection to participation and referral.

Conscientious convictions and objections derived from such convictions to participation in lawful medical procedures can be based on a variety of grounds, such as personal philosophies, a sense of social justice or equity, and perceived standards of professionalism. In modern times, however, religious convictions and perceptions often underpin conscientious objection to a range of reproductive health procedures, of which induced abortion is the most prominent. In some settings, opposition to induced abortion serves as a "litmus test" of fidelity to a religious, social, political, or other community. It is ethical for practitioners of medicine and other professions to claim their rights to conscience and to conscientious

objection, but the profession of medicine maintains historical commitments to the service of patients whose welfare's priority is professed to be given. Many medical professional codes of ethics echo the World Medical Association's modern Hippocratic Oath by having practitioners pledge that "the health and well-being of my patient will be my first consideration". Accordingly, medical practitioners who give priority to their own religious or other interests and to promotion of a religious or moral agenda risk placing themselves in an unethical conflict, if pursuit of any such interest subordinates, denies, or impairs their patients' interests in timely access to lawful healthcare services.

Conflict of interest presents medical professionals with particular challenges of avoidance or resolution. When practitioners cannot or will not render their patients care, the ethical professional expectation, and legal expectation consistently with practitioners' assumption of a duty of care for their patients is that they will refer their patients, directly or indirectly but in crucial time, to appropriate other practitioners. Practitioners' refusal to refer, on grounds of conscience, raises key concerns of the ethics of medical professionalism, and the ethical scope of manifestations of their freedom of conscience.

FREEDOM OF CONSCIENCE

Modern bioethical principles may coincide with perceptions of human rights, since bioethics intersect with and are frequently observed to overlap with human rights principles.^{2,3} However, invocation of human rights that are embodied in laws may raise questions about unethical abuse of the power that legal rights might generate. The UN International Covenant on Civil and Political Rights (ICCPR), giving legal force to the UN Universal Declaration of Human Rights of

1948, provides in Article 18(1) that "everyone shall have the right to freedom of thought, conscience, and religion". Some analysts consider conscience as legitimate only when founded on a religion, usually the religion to which the analysts themselves adhere, while others consider religion as one inspiration of conscience along with others such as secular morality, social justice, or professional integrity.

Whether "conscience and religion" are seen as a single concept in which religion subsumes conscience or conscience subsumes religion, or as separate concepts under which, for instance, religious teaching and practice are subject to evaluation by criteria of conscience. The ICCPR Article 18(3) sets practical limits. It provides that "freedom to manifest one's religion or beliefs may be subject only to limitations necessary to protect public safety, order, health, or morals, or the fundamental rights and freedoms of others", confirming that no human right, however crucial, is absolute. Even the right to life, which, particularly in the context of abortion, is often claimed to be foundational, might be limited when it conflicts with other rights, such as to personal privacy and security.

Within the framework of regard for the rights and freedoms of others, freedom of conscience, founded on whatever convictions, justifies respect, for instance through the principle of reasonable accommodation. Some significant commentators on medical practice deny that there is any justification for allowing conscientious objection to patients' requests for lawful services,^{4,5} but ethics and laws, for instance on employment, require that reasonable efforts be made to allow those responsible for delivery of services to decline participation in any they find offensive to their convictions of conscience. For instance, hospitals should have available alternative providers when gynecologists disclose in

advance, as they should, by volunteering information or in response to prior questioning that they object to perform or direct participation in abortion.

Timely disclosure of conscientious objection is ethical to provide and to require, in patients' and providers' interests and in the public interest, since, as the European Court of Human Rights has held regarding abortion services, "states are obliged to organize the health services system in such a way as to ensure that an effective exercise of the freedom of conscience of health professionals in the professional context does not prevent patients from obtaining access to services to which they are entitled".⁶ Accordingly, patients and healthcare facilities need to know on which practitioners they can rely to participate in abortion procedures, and facilities should know for which practitioners they require alternative service providers to undertake patient care when practitioners, primarily responsible for the patients, decline to serve on grounds of conscience.

Health service systems must also determine to what level of scrutiny objecting practitioners will be held. Some authorities require that objection and its scope be claimed in writing, and that it be based on the teachings of an established religion or recognized philosophy, without assessing the merits of any religion or philosophy. The ethical purpose is to exclude arbitrary judgments specific to particular clinically unrelated patient characteristics, such as patients' marital status or place of residence, and unrelated to a systematic body of thought. Conscientious objection is entitled to respect and accommodation when claimed with ethical integrity, but might be abused if founded on eccentric idiosyncrasy, and cannot be allowed to be a shield for unethical or unlawful discrimination against patients. Integrity is negated, for instance, when

practitioners invoke conscientious objection to participate in procedures in public hospitals or comparably publicly funded settings that create public records, but participate in procedures in private fee-paying confidential clinics or for members of their own or personal friends' families.

SCOPE OF OBJECTION

Ethical concerns of professionalism arise not only when physicians such as gynecologists refuse their patients' requests for lawful abortion, but also when physicians' professional colleagues such as nurses refuse to care for patients scheduled for such procedures or to provide patients with postoperative care. Instances are known of ambulance attendants refusing to transport patients with threatened abortion in the belief that their condition was deliberately induced, and law reports in the human rights literature record hospital administrators refusing to admit or process patients seeking lawful abortion procedures, on grounds of their conscientious objection. In a widely publicized US case, a police officer refused to protect women attending an abortion clinic against angry and potentially violent protestors on grounds of his conscience.⁷ It is therefore necessary to determine the extent to which societies should ethically accommodate conscientious objection to abortion and other forms of lawful healthcare.

Courts decide in their own jurisdictions and widely influential in the world beyond such as the Constitutional Court of Colombia and the Supreme Court of the United Kingdom have defined the legitimate scope of conscientious objection for participation in abortion services to balance the ethical rights of objectors with the ethical rights to lawful care of patients. In 2008, the Constitutional Court of Colombia addressed

a case of a 13-year-old rape victim who, with her mother's support, sought termination of pregnancy lawful on grounds of danger to life and of rape. Administrators in five successive governmental health authority hospitals refused to admit her, explaining that none of their gynecologists would perform the procedure, one adding that the girl's life was not at risk, although on diagnosis of pregnancy and venereal infection she had attempted suicide. The mother took proceedings against the health authority to court. The trial judge refused to direct abortion, doubting rape by questioning whether the girl had consented to intercourse, although the law provided that a person aged less than 14 was legally considered incapable of giving lawful consent to sexual intercourse. An appeal court upheld the trial court ruling, compelling completion of pregnancy. Because the case involved the girl's fundamental rights, it was referred automatically to the Constitutional Court of Colombia.

In a comprehensive judgment, the court reversed the lower courts, made rulings on accommodation of conscientious objection and on patients' rights to lawful care, and ordered compensation for denial of the girl's rights. The ruling stated that physicians who claim conscientious objection may do so on grounds only of their personal convictions, which they must explain individually, in writing, such as in terms of the teachings of an acknowledged religion. Physicians and others cannot invoke conscientious objection with the effect of violating women's fundamental rights to lawful healthcare, and any who deny women lawful abortion services on grounds of conscience have a duty of immediate referral to appropriate nonobjecting providers. Institutions must maintain information of nonobjecting providers to whom patients can promptly and safely be referred. Institutions such as hospitals and clinics, and their

administrators and staff, cannot invoke conscientious objection to deny or obstruct lawful abortion services, or discriminate against patients requesting, or personnel delivering these or related services. The Court observed that hospitals' refusals of admission to applicants for lawful abortion on grounds of their gynecologists' conscientious objection were in effect claiming rights of institutional objection, which human rights principles and related law did not accommodate.

The Constitutional Court's rulings were echoed in the Supreme Court of the United Kingdom in 2014, in a case involving two Scottish midwives employed as labor ward coordinators supervising, but rarely personally undertaking midwifery services, including abortions to which they had conscientious objections. When their employment dispute came to the highest court in the UK, the issue concerned the legislated exemption from abortion-related tasks available to those "participating in any treatment" the legislation authorized. This was understood to cover both surgical and medical (prescribed drug-induced) abortion.

The midwives claimed conscientious exemption extending to receiving and dealing with telephone calls booking patients into the ward, the admission of patients, assigning midwives to look after them, the supervision of staff attending patients both before and after procedures, and direct provision of any additional care. In contrast, the employers urged exemption only for surgeons, anesthetists, and surgery-room nurses who would otherwise be required to serve. For medical abortions, the employers required exemption only for those administering the drugs and dealing with expulsion of the products of conception, i.e. the fetus, placenta, and membranes, but excluding administrative, management, and supervisory staff. The parties agreed that the

legislation allowed no exemption regarding treatment necessary to save the life or to prevent grave permanent injury to a pregnant woman's physical or mental health.

Since the Court acknowledged that the purpose of the prevailing legislation was to widen the scope of access to safe, lawful abortion, it interpreted the conscientious exemption provision narrowly, explaining that exemption from participation covered only what it described as taking part in a "hands-on" capacity. Accordingly, exemption applied only regarding treatment of individual patients undergoing abortion procedures, such as being present to support and assist, if medical intervention is required, for instance instrumental delivery with forceps. Consistently with the ruling of the Constitutional Court of Colombia, the "hands-on" test for conscientious objection clearly precludes such claims by or on behalf of facility management and administrative personnel, and healthcare institutions themselves.

Similarly, conscientious objectors exempted from "hands-on" performance of abortion procedures remain bound by ethical and legal duties of other aspects of patient care. They cannot invoke objection for providing eligible patients with information that termination of pregnancy is a legitimate option for their care, and are ethically restrained from responding judgmentally to patients' enquiries about or requests for procedures, such as by expression or other demonstration of condemnation. That is, they are ethically obliged to conduct discussions with patients professionally, without regard to their own preferences, and should explain their own policies of nonparticipation in such procedures while maintaining continuity of patient care until relieved by other suitable care providers. Continuity may require practitioners who decline to undertake or

participate directly in abortion procedures to undertake patients' postoperative care, as they would for spontaneous miscarriage, since this does not constitute preparation for or participation in the procedure itself.

HEALTHCARE INSTITUTIONS

It has been seen above that only direct participants in medical or related procedures can invoke conscientious objection. The "hands-on" criterion makes eligibility a personal exemption from liability to undertake procedures, as an ethical concession accommodating individuals' freedom of conscience or religion. Unless granted by specific legislation, institutions do not possess this freedom, notwithstanding the personal conscientious or religious convictions of their administrators, staff, or sponsors. It has similarly been seen above, regarding abortion and other healthcare services, that "states are obliged to organize the health services system in such a way as to ensure that an effective exercise of the freedom of conscience of health professionals in the professional context does not prevent patients from obtaining access to services to which they are entitled"⁶

However, where state systems accommodate private healthcare facilities, for instance clinics, outside governmental regulation of clinical services, such facilities are usually ethically free to deliver and/or withhold services as they please. They will usually be subject to regulation, for instance by licensing, on grounds such as of structural safety and prevention of hazards of infection and fire, but not open to control regarding which patients they will admit, and for what services. Where private facilities that are not publicly funded and have not been integrated into a public or governmental healthcare system, operate under the auspices of a religious denomination. They are ethically

free to function under the mandate and strictures of their religious sponsors, such as by declining to accommodate abortion procedures.

As against this, such private institutions, like clinics, may provide abortions in ways that are ethical at the doctor-patient (micro-ethical) level, but that challenge social ethical (macroethical) values. For instance, the International Planned Parenthood Federation-European Network successfully demonstrated that the Italian state and government were in violation of the European Social Charter, when widespread conscientious objection in public institutions left abortion inaccessible to many women. The Federation's complaint, upheld by the European Committee of Social Rights, noted that "wealthier women are inclined to avail of private clinics in Italy or in public hospitals or private clinics abroad, as they are able to afford the ensuing costs of their choice", while women of modest or no means "are forced to avail of the establishments and persons... which do not guarantee the full protection of health and hygiene that is required by the termination procedure".⁸ A related ethical matter, which justifies charges of unethical professional conduct, arises when the same practitioners who invoke conscientious objection to participate in abortion procedures in public facilities, participate for fee-paying clients in private clinics.

International human rights provisions recognize, as expressed in Article 12 of the International Covenant on Economic, Social, and Cultural Rights, "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", and states' duties to realize this right by ensuring, among other care, "the creation of conditions which would assure to all medical services and medical attention". This duty is commonly discharged by governments establishing

public hospitals and comparable facilities, and/or delegating its responsibilities to hospital and comparable corporations established outside direct governmental auspices. States are obviously responsible for the conduct of state-established public hospitals, but when states delegate discharge of their duties to nongovernmental institutions, they remain ethically and legally bound to ensure such institutions' compliance with rights of members of the communities states mandate the institutions to serve.

In some cases, such as in several of the United States of America, legislation may grant religiously sponsored institutions legal immunities from having to accommodate abortion, but this does not relieve institutions from their ethical duties to act responsibly. Law is often described as "a minimal ethic", meaning that agencies must act at least within the law, but ethics may require more than law. It is not an ethically satisfactory response to a charge of ethical misconduct to say that the conduct is lawful. There may be an abusive exercise of legal power that sustains a charge of ethical misconduct. As Pope John Paul II observed, "freedom of conscience does not confer a right to indiscriminate recourse to conscientious objection. When an asserted freedom turns into license or becomes an excuse for limiting the rights of others, the State is obliged to protect, also by legal means, the inalienable rights of its citizens against such abuses".⁹

The ethical requirement that health institutions respect the interests of members of populations they and/or governmental authorities have induced to rely upon such institutions for healthcare services was shown in a legal case from California in 1989. A rape victim treated in the emergency department of a Roman Catholic hospital complained of violation of her rights to appropriate healthcare services because she was neither

offered nor informed of her option of recourse to emergency contraception, which she described as “the morning-after pill” and the California Court of Appeal as “estrogen pregnancy prophylaxis”. The hospital invoked its legislated exemption from accommodation of abortion, but the Court ruled that prevention of pregnancy is different from abortion, and that the patient’s rights had been violated. The Court accepted the patient’s claim that her “right to control her treatment must prevail over the [hospital] respondent’s moral and religious convictions” to the extent of being informed of her right to all available forms of medically indicated care, and of timely means to acquire them.¹⁰ The hospital agreed to amend its emergency responses in compliance with this requirement.

The willingness of governments and legislators in the United States and elsewhere to legislate immunities for religiously sponsored healthcare institutions from provision of abortion and other legal services is ethically questionable. It is ethically doubtful that placing the interests of dependent, vulnerable populations of women subordinate to the interests of healthcare institutions, especially when the institutions are run by politically powerful or influential religious authorities in which women are under-represented or absent, or from which they are excluded from holding leadership office, meets ethical obligations of justice and equitable conduct. This is arguably tolerable concerning private institutions outside the scope of governmental funding and discharge of obligations of population healthcare, but violates ethical principles of justice concerning taxpayer or other publicly funded systems of healthcare provision, or in which services to patients are publicly funded. That is, institutions that receive public funds often enjoying close to a monopoly on service provision, cannot ethically be allowed to deny members of

the public lawful services to which they are entitled, even when the institutions must reasonably accommodate individual staff members’ rights of conscientious objection.

DUTY TO REFER

In the case concerning the Scottish midwives that explained the scope of rights of conscientious objection, the UK Supreme Court found the compromise between practitioners’ ethical and legal rights of objection, perhaps embodied in legislated “conscience clauses”, and patients’ comparable rights to treatment, in practitioners’ duty to refer. The Court found that “it is a feature of conscience clauses generally within the healthcare profession that the conscientious objector be under an obligation to refer the case to a professional who does not share that objection. This is a necessary corollary of the professional’s duty of care toward the patient”.¹¹ The duty to refer is confined to the doctor–patient relationship, which arises when a doctor agrees to accept an applicant as that doctor’s patient, or when the doctor is engaged by an institution such as a hospital or clinic that accepts patients, and accordingly assigns its available doctors to attend them.

When individuals directly apply to doctors to become their patients, doctors may decline without assuming any duties to refer the applicants to others. They do not have a legal duty of care to those who are not their patients, outside any legislated duties in exceptional emergencies, but remain ethically bound to treat applicants for care respectfully. Doctors might decline to accept applicants because, for instance, they are too committed to undertake care of additional patients, or the patients’ conditions are outside the doctors’ specialty. If they decline on a ground of unethical discrimination, such as the applicant’s race or religion, or a

disability unrelated to the request for care, they may incur liabilities to legal and/or professional censure for legal and/or ethical misconduct, but any sanctions imposed would usually not include offenders' obligations to find applicants other suitable healthcare providers.

A common ground of objection to referral is the concept of complicity, claiming that it is as wrong to participate in another's wrong as to commit that wrong oneself, generating the same culpability. Since for instance in the Roman Catholic religious tradition committing abortion is a mortal sin, an adherent to this faith is liable to be anxious about culpability for complicity in abortion by referral of a requesting patient to another who might perform the procedure. Such anxiety may be partially relieved by the possibility of an ecclesiastical grant of absolution, or by entrusting the request to an intermediary agency or institution that would complete a referral by identifying a suitable alternative provider, depending on the sensitivities of individual practitioners.¹² However, the "hands-on" test for accommodation of conscientious objection precludes claims to rights of objection based on complicity, since referring practitioners have no hand in any services undertaken by practitioners to whom referral is made. They do not share any responsibility or blame such practitioners may incur for misconduct in care of the referred patient, nor share any fees charged by that practitioner, since receiving fees for referral is widely condemned as professional misconduct, for conflict of interest.

Two ethical concerns confound the claim to exemption from the duty of referral on grounds of complicity. The more minor is that referral of an applicant for abortion is not necessarily for the referee practitioner to conduct an abortion of the patient's

pregnancy, but for that practitioner to counsel the patient regarding her options, of which induced abortion is one. Many instances are known of referred patients finding means or reasons to continue pregnancy, but with the assurance they seek that, should they come to prefer that choice, safe, timely termination would be available to them. The more major concern is the perceived scope of potential complicity. Practitioners may find complicity only in regard to individual patients seeking abortion, and be apprehensive of complicity in other practitioners to whom they refer such patients for terminating pregnancies, generating culpability for them as the initial referring practitioners. They are sometimes persuaded by a claimed analogy of declining a request to commit a murder, but referring the requesting party to someone else who will commit the act, rendering them morally culpable for the crime.

This analogy is false when procedures to which practitioners may object are lawful, and also because patients requesting the procedures have an ethical claim to them not only on their immediate practitioners but also on the healthcare systems in which their practitioners participate. As the European Court of Human Rights ruled, "states are obliged to organize the health services system" to ensure that conscientious objection "does not prevent patients from obtaining access to services to which they are entitled".⁶ Accordingly, the scope of complicity arises not simply from the relationship between a patient and an initial and referee provider, but between a patient, a practitioner and the health services system of which the practitioner is a member. That is, complicity is not simply with another practitioner to whom a patient is referred, but with the health services system itself that is obliged to ensure the patient's access to the lawful service to which the practitioner objects. The

medically qualified person who objects to complicity in certain clinical services would ethically be bound to forgo not just referral to another practitioner, but a career in a clinical medicine system. The objecting physician might render service instead in an alternative specialty or branch of medicine, such as a congenial branch of medical research or education, or for instance in management of an acceptable healthcare facility, to escape guilt for complicity in a system bound to satisfy patients' requests for lawful abortion.

A wider ethical consideration arising from the duty to refer is that an objector's referral of a patient requesting abortion to a suitable colleague who agrees to accept the referral relieves in part the burden that conscientious objection might impose on a hospital- or clinic-based practitioner's non-objecting colleagues, and on the prevailing regional healthcare system. The ethics of conscientious objection and transfer of patients by referral imposing a disproportionate burden on nonobjecting colleagues was addressed in a decision finding that the Italian state's failure adequately to redress widespread resort to conscientious objection violated the European Social Charter. The European Committee of Social Rights found Charter violations regarding not only women's rights to timely, locally accessible abortion services, but also medical providers' rights.

In the case brought by the confederation representing Italian workers, the complainant succeeded in showing that failure in particular regions, particularly of southern Italy, to recruit enough medical practitioners who did not object to participation in abortion procedures placed nonobjectors under an excessive burden of work. It similarly denied them career development by confining their professional experience to conducting only abortion services, often compelled them to work without colleagues' assistance, and

denied them dignity by exposing them to stigma and moral harassment.¹³ This finding reinforces the charge that, while reference might be an ethical compromise between patients' rights to care and practitioners' rights of conscientious objection, refusal to ensure suitable referral can unethically impose burdens on professional colleagues.

VOLUNTARY SURRENDER OF RIGHTS

It has been seen that state-sponsored or state-supported healthcare systems and healthcare facilities acting under their auspices, such as by delegation of authority, bear dual ethical responsibilities of reasonably accommodating health service providers' rights of conscientious objection, and of ensuring that claims to rights of objection do not jeopardize patients' rights of timely access to the lawful health services to which they are entitled. While health service practitioners are ethically entitled to invoke their rights of conscience, however, they are not ethically obliged to invoke them. A model of voluntary surrender or suspension of rights is afforded by practice within the Roman Catholic tradition.

The UN International Covenant on Civil and Political Rights, in Article 18, protects freedom of thought, conscience, and religion. Article 23(2) of the same Covenant recognizes "the right of men and women of marriageable age to marry and to found a family". This right, included in the 1948 Universal Declaration of Human Rights, was given legal force in light of earlier experience, in Europe and elsewhere, of countries legally prohibiting classes of persons from marriage, and implementing nonconsensual sterilization programs designed to preclude individuals' parenthood. The freedom of eligible persons to marry and found families is often

considered fundamental since, as Article 23(1) of the ICCPR provides, “the family is the natural and fundamental group unit of society and is entitled to protection by society and the state”.

The Roman Catholic Church does not deny the right of marriage and parenthood, but provides in modern times that those who exercise this right cannot follow the calling to serve for instance as priests or nuns (with limited exceptions for married clergy who later convert from other Christian denominations). Individuals’ pursuit of the calling to serve in the Church in defined capacities is conditional on their voluntary surrender of rights to marriage and procreation of children. If married, they cannot take these roles in the Church (except as above), and pursuit of such rights while holding office requires that they depart from representative Church office and resume their lives as members of the laity.

The ethical question is whether healthcare facilities might similarly condition staff appointments on voluntary surrender of rights of conscientious objection, or if not of complete surrender then of claims of conscientious objection to referral. The UK Supreme Court described referral as part of practitioners’ legal duty of care, and health facility staff cannot ethically require that they be allowed to deny patients their legal rights to due care. Observance of patients’ rights, including to referral for care that practitioners agreeing or appointed to care for them cannot or will not provide, is a legitimate condition of healthcare facility employment. By refusal to meet patients’ rights to treatment or referral, potential staff-members render themselves unemployable in such facilities. Facilities have reciprocal duties of reasonable accommodation of rights to conscientious objection, so a requirement of complete surrender of practitioners’ rights may be unreasonable when alternative

provisions can be made for patient care, but surrender of rights to refuse referral might be the reasonable compromise, as courts and professional ethical guidelines indicate. Similarly, sole practitioners unethically abandon their patients whom they will neither treat nor refer.

For instance, the FIGO ethics committee guidelines on accommodation of conscientious objection open with the recognition that “the primary conscientious duty of the obstetrician–gynecologists...is at all times to treat, or provide benefit and prevent harm to the patients for whose care they are responsible. Any conscientious objection to treat a patient is secondary to this primary duty”.¹⁴ The guidelines on referral provide that “patients are entitled to be referred in good faith, for procedures medically indicated for their care that their practitioners object to undertaking, to practitioners who do not object. Referral for services does not constitute participation in any procedures agreed upon between patients and the practitioners to whom they are referred”.¹⁴ To give effect to the opening provision of the guidelines, ensuring patient care, they continue “practitioners must provide timely care to their patients when referral to other practitioners is not possible and delay would jeopardize patients’ health and well-being, such as by patients experiencing unwanted pregnancy”.¹⁴

Obstetrician–gynecologists who would not accept the professional priority of patients’ welfare and the ethical commitments this entails, nor compromise their own convictions by suitable referral, cannot ethically undertake clinical responsibilities of patient care. Their refusal to yield their objection to render emergency care, or to referral of patients to other suitable providers, amounts to voluntary surrender of rights to bear clinical responsibilities. Their careers as

clinicians may be preserved, however, if third parties such as their colleagues, healthcare institutions, or professional associations will invariably intervene to complete their patients' appropriate, timely referral. Government agencies that directly engage services of potential conscientious objectors might take initiatives to identify referees for their patients, because courts might rule that state agencies cannot make exercise of rights, such as to nondiscrimination in employment, conditional on foregoing other rights, such as to conscientious objection.

MEDICAL MONOPOLY

It would be incongruous and unethical for a medical professional association to claim a monopoly over services, patients may lawfully request, notably abortion, when the association allows its members rights of conscientious objection to refuse both to deliver such services and to refer patients to receive the services from other suitable and available practitioners. The claim that only trained members of the medical profession should be able to deliver services, usually understood to mean surgical interventions, is often justified on ethical grounds of ensuring patient safety, even when the known effect of allowing widespread conscientious objection is that patients with financial means travel for abortion services to other countries, including those where safety is not assured, and those without means resort to local unqualified, unskilled, and/or unsafe providers. Similarly, governmental healthcare systems violate ethical and human right norms when their creation and enforcement of physicians' legal monopoly on service delivery leaves vulnerable patients dependent for care on practitioners whose rights of conscientious objection are so comprehensively invoked as to deny patients practical means of access.

A medical monopoly on abortion services may ethically and legally accommodate nonphysician participation, even to the extent of substantive management of the actual process of pregnancy termination. The highest court in the UK has recognized that physicians may remain formally in charge of procedures along extended lines of delegated authority when others such as nurses conduct the physical management of patient care. When the Abortion Act, 1967 gave immunity against criminal liability for abortion to only "a registered medical practitioner", nurses claimed that they remained unprotected and therefore could not participate in prostaglandin-induced abortions. However, the government department regulating health services successfully argued that nurses were legally protected when acting under physicians' authority and direction. Physicians would assess patients' suitability for the procedure and insert catheters through which nurses would administer the required drugs, and then manage the consequent expulsion of uterine contents, completing the abortion. Initiating physicians would remain available to treat any unexpected complications, serving in a supervisory capacity.¹⁵

One reaction to practitioners' refusal of abortion services they are qualified but object to deliver, directly or by delegation, has been for other physicians to form a conscientious commitment to provide such services (see Conscientious Commitment below), as a matter of social justice and to give witness to the professional claim to promote patients' welfare.^{16,17} Another ethical response to the unavailability of qualified physicians to serve the needs of applicants for care, whether due to their absence or to the conscientious objection of accessible practitioners, is for healthcare systems under governmental control to equip lesser but adequately

qualified personnel to be available to deliver services.

Provision of such additional personnel is sometimes described as “task shifting,” introducing so-named “mid-level providers” to ease denial or delay of patient care due to the medical monopoly on service provision. For instance, midwives, nurse practitioners, and other specially trained nurses might be provided to undertake first trimester abortions, such as by vacuum aspiration methods, or nonsurgical (medical) abortions by use of mifepristone and misoprostol. They would be trained to recognize the limits of their skills and to refer patients experiencing complications beyond providers’ capacities to manage to facilities fully equipped with nonobjecting physicians and related staff.

An ethical responsibility of nonobjecting practitioners where midlevel providers are introduced is to participate in training them to deliver safe and effective care. A model for training midlevel providers exists in the FIGO ethics committee recommendations regarding task-shifting in obstetric care.¹⁴ These were developed against a background of low-resource settings where obstetricians are unavailable, but the description is also applicable to settings where gynecologists are amply available but predominantly object to participate in abortion procedures in public hospitals and clinics serving less affluent communities, such as in southern Italy. Adequately trained midlevel providers could serve as a communal resource for delivery of abortion-related services, such as management of retained products of conception, and services beyond abortion, such as to treat menstrual irregularity. Similarly, the FIGO recommendations include that midlevel providers of obstetric care could also be trained for delivery of abortion care. They observe that “task-shifting has been found to be beneficial particularly if

there are appropriate and adequate training, good implementation, adequate support, and continuous monitoring and evaluation of outcomes.”¹⁴

Where medical (that is nonsurgical) abortion is lawful and available, patients may be prescribed the required medications by general medical practitioners educated in their use, and by trained midlevel providers who similarly ensure applicants’ eligibility for this treatment. Such providers or, for instance, trained nurses would counsel patients about choices of when and where to take the medication and how to manage the consequences, such as to ensure that any retained products of conception are removed. If necessary, follow-up care may be sought by resort to hospitals. Hospital staff who conscientiously object to participate in initiation of abortion procedures cannot ethically maintain their objection to post-operative care, since they would be no more complicit in initiation of procedures for termination of pregnancy than they are in spontaneous miscarriage, nor necessarily able to distinguish induced from spontaneous miscarriage. However, while laws retain a medical monopoly of abortion services and the trappings of criminality, requiring for instance certification by two qualified physicians that medico-legal criteria for access to lawful abortion care are satisfied, practitioners are ethically bound to observe the law in their practice, although individually and through their professional associations they may join with others to advocate for change.¹⁸

CONSCIENTIOUS COMMITMENT

An aspect of conscientious objection, though paradoxically the reverse of conscientious objection as it is traditionally understood, is objection not to performance of lawful

procedures such as abortion but ethical objection to compliance with institutional directives¹⁹ or customs that require refusal of patients' requests for such procedures, or withholding of information or advice about and/or of referral for such procedures. This is increasingly described as conscientious commitment. Protection of conscience includes ethical protection of conscientious commitment, because traditional conscientious objection, often religiously inspired, does not have a monopoly on conscience.¹ Conscientious commitment is ethically different from civil disobedience, since commitment is to performance of lawful procedures, not those prohibited by criminal law, although performance of procedures, including related informing, advising, and referral, is condemned by some institutional directives usually conditioned by religious doctrines.

Where institutions such as hospitals are legally prohibited from discriminating in recruitment of health service personnel on grounds of religion, including hospitals established under the auspices of religious denominations, their health service staff will often include members who do not personally adhere to the particular religious denomination or religion of the institutional establishment. Appointment of hospital chaplains will legitimately be religion specific, of course, but regular health service providers might include some who conscientiously object to compliance with religiously inspired directives when they find them inimical to their patients' best interests. Serving patients' conscientiously assessed best interest keeps faith with the World Medical Association's 2017 version of the Hippocratic Oath, the declaration of Geneva, now called a "pledge," which opens with the provision that "the health and well-being of my patient will be my first consideration".

For instance, practitioners might ethically consider that ectopic or tubal pregnancy must be terminated with patients' consent promptly on diagnosis, without any delay required by institutional directives, which might condition termination on imminently threatened rupture of the fallopian tube, or by referral to an institutional ethics committee or a medically unqualified senior religious official.

Not all countries have religiously affiliated hospitals, but in those that do, the intervention of religious doctrines and attitudes might seriously prejudice women's access to medically indicated care. Studies have shown refusals of therapeutic drugs to informed consenting women due to practitioners' concerns for embryos or fetuses possibly or actually existing in utero, and life-endangering delay in treatment when pregnancy of a nonviable fetus showed a heartbeat.²⁰ They similarly show that survival of patients suffering cardiovascular, cancerous, and comparable diseases that make continuation of pregnancy contraindicated might be discounted in favor of fetal preservation.²¹

The ethical and legal provision of equality under the law requires that secular and religiously affiliated hospitals treat their service delivery personnel with equal respect. Secular hospitals should reasonably accommodate the conscientious objections of objectors, without discrimination or sanction, and religiously affiliated hospitals should reasonably accommodate the commitment of personnel dedicated to serve patients' best interests as they conscientiously perceive them, equally without discrimination or sanction. The expectation that such accommodation be "reasonable" means, for instance, that objectors be required to deliver necessary care in emergency to which they ordinarily object, such as when nonobjectors

are unavailable, and that conscientiously committed practitioners not compel participation in procedures by necessary supporting staff, such as anesthetists and nurses, to which such staff members personally object. They may provide abortion-related information, counseling, advice, and/or referral, but not undertake procedures that require objecting colleagues' collaboration.

In some institutions whose management opposes abortion, and for instance by some state laws in the US, women seeking abortion are required to be given dissuasive information or counseling to deter them from pursuing any abortion options. In Germany, the court of leading constitutional authority, followed by the comparable court in Portugal, required explicitly dissuasive counseling of women having abortions as the state's acknowledgement of the value of unborn human life.¹ Conscientiously committed staff members do not encourage abortion, but are committed to women exercising their free, appropriately informed choice.

A requirement to provide scientifically correct information is usually unobjectionable, and need not be legislatively mandated where the standard rules of informed consent to medical treatment are applied, but some mandated information is intended to deter choice of abortion options by its alarmist, threatening and/or biased, unfounded or false content.^{22,23} Where compulsory speech laws apply, practitioners must usually conform, but ethically they are entitled to present additional, correct information that exposes false, politically designed statements that they are required to present. Compelled speech does not negate practitioners' right to free speech, and in reciting any legally mandated script or formula, they are entitled and even ethically bound to inform patients that the compelled statements are politically motivated. They

may supplement the compelled speech with additional nondirective information required by customary medical ethics and integrity for patients' exercise of free choice.

Practitioners might face an ethical dilemma where legislation requires them to give specific information or, for instance, to conduct and show ultrasound examinations picturing a fetus in utero. Ethically, practitioners should offer information and procedures such as examinations, advising on their utility, without compelling patients' acceptance. Explanations and examinations should be offered as opportunities for patients freely to accept, not as obligations to hear, see or otherwise endure. Practitioners might find it unconscionable, for instance, to risk abortion patients' well-being by implementing the Guidelines on Psychological Pre-Abortion Counseling issued in 2010 by the Russian Ministry of Health and Social Affairs, which describe the procedure as "murder of a living child".²³ The design by governments, legislatures, or others to deter, or to punish, induced abortion by afflicting women with guilt and distress should not cause violation of the transcending medical ethic to Do No Harm, to which practitioners may conscientiously object.

Conscientiously committed practitioners must ethically be respectful of their patients' perceptions and values, acting only with patients' free and informed agreement to undertaking or forgoing procedures. For instance, the status attributed to human embryos and the point at which the life of an individual person begins will remain contentious and unresolved while different philosophies, religious traditions, and perceptions prevail. The FIGO ethical guidelines, for example, provide that "pregnancy commences with the implantation of the conceptus in a woman, and ends with either the birth of an infant or an abortion".¹⁴ Development

of human in vitro fertilization (IVF) spread understanding that fertilization precedes pregnancy identified at implantation, with the consequence that prevention of implantation does not constitute abortion. However, those who equate fertilization with conception, and believe that human life requires protection from fertilization/conception, will oppose techniques of fertility control that obstruct implantation. Addressing IVF, the Inter-American Court of Human Rights has rejected the argument that fertilization and conception are concurrent and synonymous, observing that “the term “conception” cannot be understood as a moment or process exclusive of a woman’s body”, and ruled that conception “occurs at the moment when the embryo becomes implanted in the uterus.”²⁴ Nevertheless, patients should be informed of the possible effects of methods of contraception, such as insertion of intrauterine devices (IUDs), and be allowed to reject any they find unacceptable as abortifacient.

CONCLUSION

The greatest ethical challenges of conscientious objection and related referral are at the extremes. Acceptance of the view that conscientious objection to lawful procedures has no place in the voluntary assumption of responsibilities of clinical care of patients has credible support among some bioethics analysts, and is applied in a few national healthcare systems. However this approach, without practitioners’ voluntary surrender of their rights, risks offending human rights principles of reasonable accommodation of diversity in employment settings. Where practitioners conscientiously motivated by different ethical convictions are committed to professional collegiality, responsibilities of patient care can be distributed to maintain both patients’ appropriate care and practitioners’ conscientious values. At the

other end of the spectrum from absolute exclusion of conscientious objection is absolute refusal not only of any association with practices considered objectionable that patients are legally entitled to receive but also of referral of patients, for whom practitioners have accepted duties of care, to other practitioners who do not object. Holding patients captive by refusal of referral, such as by invoking concepts of complicity in what other practitioners are willing to undertake, risks denial of patients’ rights to care, and to the information they require for protection of their health and well-being through access to appropriate service providers. At its extreme, conscientious objection has been unethically invoked by health facility administrators and facilities themselves to deny applicants for care admission to receive the range of medical services on which the facility managements have induced them, as community members, to be dependent.

The commonly acceptable compromise between practitioners’ conscientious objection to direct, i.e. “hands-on”, participation in treatment and patients’ rights to care is through objecting practitioners’ duty of referral. This is almost universally endorsed in medical professional codes of ethics, and widely underwritten by legal provisions. Practitioners who invoke concepts of complicity to refuse referral are objecting not only to their own patients’ receipt of care, but to participation in systems of clinical healthcare that are ethically and legally bound to ensure all patients’ access to such care. That is—they are refusing to participate in a healthcare system that must make available the clinical care in which they refuse to feel complicit. They thereby disentitle themselves from ethically inducing patients’ dependency on them for clinical care to which patients have ethical and legal claims.

Patients’ dependency raises particular ethical concerns when practitioners liable to

refuse treatments on grounds of conscientious objection, and the facilities in which such practitioners are engaged, are publicly funded. Recipients of governmental funding for delivery of healthcare services to the public are not free in principle to select which members of the public they will serve and from which they will withhold services. A leading American judge has observed the harmful effects to individual and communal well-being and sense of security caused by “the loss of public confidence in governmental protective services if the public knows that its protectors are at liberty to pick and choose whom to protect.”⁷

When governments fund public healthcare through practitioners and/or facilities that operate according to religious denominational rules or directives, governments are accountable to ensure means by which applicants for care that such practitioners or facilities decline to render will have access to alternative sources of timely treatment. If governments are more deferential to religious hierarchies that operate healthcare facilities as part of their pious mission, such as by governmental grants of immunity from legal liability for refusals of care, than to the public they claim to serve, deficits in patients’ access to contentious services are liable to arise, as experience shows in different parts of the world.²⁵ At an individual level, practitioners bear the ethical challenge of resolving whether, and if so how, they will respond to this governmental neglect or disregard of patients’ requests for types of lawful care that raise conscientious objections and the related need for referral to willing and available providers.

For the future, it has to be asked whether the expansion of medical abortion will in time take all but infrequent complicated and late-term abortion procedures out of hospitals, and even out of the hands of gynecologists.¹⁸

Free-standing specialized clinics staffed by trained midlevel providers without conscientious objections, acting where legally required under the extended authority of general medical practitioners, might be promoted as governmentally funded services to supply critical drugs and attendant care, backed when necessary by public hospitals. The UK National Health Service (NHS) now operates on such a basis, where “abortion is disappearing from the workload of many gynecologists in England and Wales.”²⁶ This development might reduce the incidence of ethical concerns and conflicts over abortion-related conscientious objection and the duty to refer, although withdrawal of all but a few abortion patients from hospitals raises the ethical concern that “an imminent crisis in service provision is likely because training in abortion care is simply no longer available... for most junior doctors.”²⁶

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Current Ethical Challenges Facing the Obstetrician-Gynecologist: Conflict of Interest

Ralph W Hale

INTRODUCTION

Today's obstetrician-gynecologist faces many challenges in their daily practice.

Many of these relate to a decision in the diagnoses of conditions occurring in the women they treat. These decisions occur when they recommend diagnostic tests, make a diagnosis and decide if to treat or whether to refer to other physicians for more advanced or specialized care. As part of their training, physicians have been taught the appropriate way to manage this decision-making process and usually it occurs with few questions. For the patients they care for and treat, there are also decisions about what diagnostic test, if any, or procedures are necessary and appropriate. Once the diagnosis is established, then decisions must be made as to which therapy or nontreatment should be recommended. This may result in either dispensing a medication or writing a prescription for the medication which the patient can take to another entity to receive her medication.

These decisions occur numerous times during a practice day and each has an impact upon the patient and the care that she receives. Physicians should always make informed, disinterested judgments when dealing with their patients.¹ This requires any decisions to be free of personal advantage. In the vast majority of situations, the obstetrician-gynecologist makes these decisions based

upon their training, experience, practice routine, current situation, and available resources. The patient on the other hand has very little knowledge or understanding of the myriad of processes that the obstetrician-gynecologist has used to make the decision and the recommendation that they are making to the patient. They rely upon the obstetrician-gynecologist to make the best and right recommendations. This is based upon an interpersonal relationship that forms and is the basis for the physician patient interaction as well as a key to how her obstetrician-gynecologist is viewed by the patient.

This relationship is critical for both the patient and the physician. The patient is placing the physician in a position to control some aspect or all of her future life. It may be as simple as a decision that occurs in a well woman visit, which found no problems and reassures the patient she has no current serious concerns; thus allowing her to continue with her life as before. Or, it may require her to accept that she has a condition that is not normal and may necessitate an intervention that the obstetrician-gynecologist will recommend. For the physician, this is all part of their care for the patient. For the patient, this is or could be a change or an alteration to her future life. The degree of seriousness of this recommendation can have

ramifications for the patient, her immediate family, and even her extended family.

Very few decisions that the patient makes in their daily life will have the extensive impact on that life that a finding by an obstetrician-gynecologist may have. In order for the patient to accept any decision or subsequent recommendation, she must have trust in her doctor. Since this trust can and often does alter her future life, the obstetrician-gynecologist is in a unique position in the woman's life. In many or most situations, the patient also has no knowledge or understanding about what has been reported to her or suggested by the obstetrician-gynecologist. As a result, she must rely upon the trust that she has in her doctor and in relying on that trust accept the decisions that will follow.

The obstetrician-gynecologist must recognize that the patient is using this trust to accept what is being recommended. This is a heavy burden that is being accepted by her doctor and being given by the patient. Therefore, it is critical that every decision, every recommendation, and every procedure is based on the best and most current knowledge available. This requires the obstetrician-gynecologist to avoid any action, which is influenced by anything that would betray that trust.

The area of most concern in this interpersonal relationship is whether there is any outside influence that is affecting the decisions. In other words, is there an unknown influence in this decision-making process that is impacting upon any aspect of the women's healthcare?

In this chapter, we will explore multiple aspects of the potential influences in order to help the obstetrician-gynecologist or any physician understand the impact that any influence, usually referred to as a conflict of interest can have on their practice decisions.

The International Federation of Gynecology and Obstetrics (FIGO) has a position

statement on conflict of interest for its officers and committees to assure that FIGO documents and actions are not influenced by outside sources.² A number of FIGO member societies have similar policies that require their members to abide by the society conflict of interest policy in the work of the society as well as with their patient activity.³ In some countries such as the United Kingdom, where the FIGO office is located, regulatory officials also have conflict of interest policies that the organizations under their purview are required to follow.⁴

Conflict of interest in the practice of obstetrics and gynecology can have major impact on all aspects of patient care. As this issue is explored and explained in subsequent areas of this chapter, it is the intent to alert obstetricians-gynecologists to the potential of conflict of interest in their practice and how to manage situations that arise. No obstetrician-gynecologist is immune to the potential for conflict of interest, regardless of where or how they practice.

DEFINITION

A physician has a duty to their patients to offer and/or recommend the most appropriate care for the patient. A key factor is that it does not do or appear to do any harm to the patient. This premise has long been a pillar of medical practice and traces its origins to the time of Hippocrates. The concept has been stated clearly as "physician do no harm". Medical knowledge has grown rapidly in the last 50 years and with that growth there has been increased reliance on other healthcare resources that the obstetrician-gynecologist can utilize while involved in delivering patient care. These resources include laboratories, outpatient and inpatient medical/surgical facilities, pharmaceutical and equipment companies plus multiple additional other outside companies that may be used to

assist in diagnosis and care of the patient. The obstetrician-gynecologist practicing in the 21st century will rely upon some or all of these available resources in order to offer the best healthcare to their patients.

Most of these identified resources are either owned by a large corporation or by a smaller independent company. With a few exceptions all of these companies are designed to be a profit-making enterprise. When utilized by the obstetrician-gynecologist in their practice, it is a source of income and potential profit for that company and its owners. In some of these relationships the obstetrician-gynecologist may establish a working partnership or may have a full or partial ownership. When this occurs, the care of their patients can be influenced by that relationship. If this occurs then a potential financial or other benefit to the physician may occur and become the rationale behind the referral of patients to the specific company or utilization of their services. This would result in what is commonly referred to and defined as a conflict of interest. Conflicts of interest arise in those situations when a physician or researcher's professional judgment concerning a primary interest is at risk of being biased by a secondary interest, resulting in possible harm to a patient or the integrity of research.⁵

This term, conflict of interest, is usually used when it describes any interaction where an individual physician's professional responsibilities are or have the potential to be compromised by other obligations or relationships because of financial reasons. This compromise may or may not result in possible harm to the patient. Although not recognized as clearly as financial impact, a conflict of interest can also exist when professional judgment concerning a primary interest is affected by a nonfinancial secondary interest. If a physician has a conviction or belief regarding a certain treatment that

causes them to overlook or select alternatives that are less effective, then a conflict of interest has occurred. An example is the recent debate on the role of vaccines as a cause of autism in children. Belief in this erroneous theory can prevent the proven health benefits derived from the use of vaccines and the resulting harm that can result to patients and nonpatients in the community.⁶ Although money may not be the only benefit, in most cases, it is a direct financial benefit to the physician that results in a conflict of interest. In general, a financial benefit occurs when the physician has a direct or indirect relationship through business, investment, or family that results in direct or indirect compensation or other remuneration.⁵ This can be in the form of direct payment, gifts, favors, travel, etc. It may also be in the form of a benefit to their immediate family, including siblings, parents, or other relatives. The fact that the physician is receiving the benefit indirectly does not alter the existence of a conflict of interest.

There are many areas in the obstetrician-gynecologist practice that can be influenced by outside influences. There are also personal business relationships, such as owning a laboratory that can affect the physician's actions. In any patient care situation where a decision or action can be influenced by a financial or other interest, a conflict of interest will or has occurred.

Since the most common understanding of a conflict of interest is one that results in direct financial benefit to the obstetrician-gynecologist, it is the one most often recognized as a conflict of interest. In addition, there can also be a perceived conflict of interest. This occurs when the physician has a close relationship with the company or an individual and utilizes their services. This is not often recognized but the obstetrician-gynecologist should be aware that it exists

and, if necessary, identify the relationship. The fact that a conflict of interest may be incorrectly perceived to exist does not create a conflict of interest as there is no risk of bias. However, the perception can lead to an erosion of confidence. Whenever it is “perceived to exist”, it is best to disclose and explain that there is no conflict of interest instead of ignoring the problem.⁵

Based on the results of either a direct or indirect benefit, any action by the obstetrician-gynecologist related to any aspect of patient care may be a source of a conflict of interest. The most common areas will be discussed later as some of the areas, which have been identified.

Sometimes you hear the term “potential conflict of interest”. This is a misconception as there is either a conflict of interest or there is no secondary interest to bias the physician judgment.⁶ Although all conflicts of interest are not necessarily bad or wrong and in some cases could result in better or more appropriate care, they must be identified to the patient or audience to avoid any perception that what was offered or recommended was the result of a conflict of interest. Identification and transparency remain the key to understanding and validity of care and avoiding conflict of interest.¹

CONFLICT OF INTEREST AREAS

One area where conflicts of interest can easily arise is in the ordering or dispensing of medications. For most conditions that are treated by the obstetrician-gynecologist, there will be more than one recommended pharmaceutical preparation currently available. There are many reasons to prefer one drug rather than any other. The usual reason is familiarity with the side effects and mode of action. Others include cost, ease of use, availability, and past practice. The important factor to consider is what is best for the patient. The

physician should not base the prescription on the pharmaceutical representative or company producing the medication because they participated in a continuing medical education (CME) course paid for by the company or were given a nice desk set by the company or were hosted at a nice hotel in a resort area where they learned about the medication or even at a local meal with a company presentation. All of these would be an actual conflict of interest. In the past and occasionally now, companies use these types of incentives to convince obstetricians-gynecologists to use their specific product when the scientific literature shows either equal or better results with a competitor’s product.

Of all of these incentives, food and beverages are the most frequent types of gifts and payments from industry to physicians.⁷ They provide these meals expecting a return.^{8,9} Even small gifts, less than \$20 (USD) meals, e.g. can be a significant influence on physician behavior as they create a mindset of entitlement.¹⁰ As the amount of the gift increases, the reaction of the physician in favor of the company’s products increases. On the other hand, there is no lower limit to where a gift or meal impacts on the prescribing of a company’s product. It has been shown that physicians receiving even a single meal promoting a drug had a high rate of prescribing that particular drug.¹¹ In these situations even a conflict of interest statement does not seem to influence behavior as much as the gift from the company. It is best to avoid all such presentations.

Ownership of a laboratory is an increasing area where the obstetrician-gynecologist can have a conflict of interest. Simply by ordering a blood test and sending the patient to a laboratory where the physician is an owner or part owner creates a conflict of interest. If the laboratory is profit making, the physician will ultimately benefit, so the

patient should be aware of other options and that the physician has a business or personal relationship with the laboratory. The same can happen with a surgical outpatient center or an ultrasound office or any other procedure-oriented business. It may be that this is the best option for the patient, but she should be aware of what options she may have and that her obstetrician-gynecologist does have a financial arrangement with the recommended facility. It is less obvious, if the physician is only a stockholder but again, transparency should be followed, so the patient has full knowledge.

Similar to medications, clinical research grants can also create the appearance of a conflict of interest. If a company is supporting a trial of a new medication and pays the physician to enroll patients there should be a clear understanding by the patient that if she agrees to participate her physician will be receiving a payment because she enrolled. Since in most of these grants, the patient receives free medication and may be even free care, this is an obvious benefit to the patient. However, if it is not transparent that the physician is also benefitting financially then there is a conflict of interest.

Indirect financial support is another area where conflict of interest can occur. A well-known pharmaceutical company representative called me a few years ago about a new medication delivery system that the company had been approved to market. They encouraged me to use the system and in return they would place my name on a select panel of obstetricians-gynecologists that they were listing on their website explaining the new system; the website explained the systems reported benefits. There was further information identifying how to contact these practitioners that were utilizing the new system with their patients. I was informed that previous experience with this type of website

had resulted in increased patient visits. Since I was not receiving any payment from the company, they assured me that there was no conflict of interest. What they did not say was that there were other medications available for use for the same condition that were well researched, much cheaper, and just as successful in treating the patient. I was not convinced and believed then and now this was definitely a conflict of interest. Advertising is certainly a legitimate activity, but associating your name with the advertising to increase use of a specific medication or procedure is still a conflict of interest. It is always appropriate to visit exhibits or receive promotional material about new products or equipment. This is a way to remain up-to-date and aware of all options. What is not appropriate is to receive something of value from the company and then modify your care for a patient as a result.

Continuing medical education is another important area that is frequently a source of conflict of interest. Fortunately, most accrediting bodies now require reporting of any conflict but it is often done in such a way that the audience pays little attention. Presentation of a slide rapidly removed from the screen that describes a relationship with a company or product does not adequately explain a conflict of interest. Any speaker giving a scientific presentation about a medication or procedure or instrument should disclose all aspects of any relationship that they have with the company, even if they are not paid by the company or speaking for the company. I attended a recent CME lecture by a professor of obstetrics and gynecology where there was a detailed presentation on a specific way to treat the condition that was the subject of his lecture. There was no disclosure and the professor carefully outlined separate ways that the condition could be managed and with the several different medications

that could be used. During his conclusion, he recommended one of the mentioned medications as his preferred treatment and the one he would use first as it was the one he had personally had the most success in using while treating his patients. Only later did I learn that he was a paid consultant to the company whose medication he had recommended. I believed that this was a definite conflict of interest and yet no disclosure was stated because there was no payment by the company for this particular lecture. This was not transparency, even if he was recommending the correct medication as the best way for treatment.

A related area is the promotional presentations by respected academic, research, or practicing physicians, which are designed for increasing the use of a medication or procedure, many of them, but not all, are supported by a commercial interest. These are rarely prepared to give a “balanced view of therapeutic options.”¹² The payments to the speaker plus the cost of the venue and meal are based upon the value of the perceived increased prescriptions generated, rather than an appropriate evaluation of clinical significance. Often the slides and presentation material have been prepared by a company and are designed to bias the audience to a specific therapy. The fees to the speaker are based on an ability and opportunity to convince the physicians in attendance of the value of the product. The honorarium received by the speaker and the gifts to the attendees, if any, encourages a biased presentation and reception in favor of the company product. Most such presentations are not CME approved, but this does not detract from their influence on the audience.

During the latter half of the 20th century and now into the first quarter of the 21st century, the growth of medical knowledge has

escalated. As a result, Medical Licensing Boards in many of our member societies now require the physician to obtain accredited CME in order to maintain an active license. Much of this CME is based upon presentations and journal articles provided by physician experts and researchers. In the USA, the Accreditation Council for Continuing Medical Education (ACCME) has developed requirements to assure acceptable approved credit is obtained by physicians licensed to practice in the US. Other countries have also adopted similar bodies and systems. The purpose is to address and prevent any biased information. Special attention is directed at any relationship with a pharmaceutical or instrument company. The sponsoring organization must require the presenter in these CME presentations to disclose any conflict of interest, if present, and have a mechanism for management. There are limitations to these actions. First the disclosure is restricted and secondly it only focuses on financial relationships, thus ignoring other sources of bias.¹³ In these presentations, it is imperative, even if disclosure is stated that the participant be aware of any signs of bias or misdirection. This is extremely important when the accredited activity has commercial support or sponsorship.

Another potential for conflict of interest is in the area of educational grants. Many of these are given by companies to assist candidates from lesser developed countries or residents in training to allow them to attend major meetings. Rarely do they involve any mention or recognition of the company support and contain no requirements for further action. However, it does make the recipient feel obligated to the company in their future practice activities. Therefore, reporting and indicating that such a support was given should be part of the individual physician’s notification when they are utilizing the company medication.

There is no situation where conflict of interest is more important than in committees or panels of professional medical societies that develop practice guidelines.¹³⁻¹⁵ Practice guidelines are often utilized as the basis for developing standards for quality medical care. They are also utilized by insurance companies and government agencies when they establish policies to approve eligibility and payment. They are also cited in legal proceedings as well as medical error cases. Their impact is seen in almost every obstetric and gynecologic practice on a regular basis and they can have significant effect on all aspects of patient care. Guideline developers attempt to use extensive literature based on published peer-reviewed research related to the specific condition under development in making their recommendations. However, not all clinical situations have significant credible peer-reviewed research available in order to allow for specific recommendations. In those situations, the developers will usually rely on the clinical judgment of the panel or committee members developing the guideline. It is this area where personal bias can result in a conflict of interest. For this reason, any member involved with guideline development must be free of any outside influences that could affect their decisions.¹³ It is not sufficient for members to just list a conflict of interest. When a conflict of interest is reported or exists, the individual should not be allowed to be in a position to be a decision maker for the guideline.

These are just a few of the many areas where a conflict of interest may also occur. There is one area, however, that is often overlooked. Family relationships can lead to situations where a conflict of interest occurs. The spouse or children or other family members can work for a company that produces medications or equipment that the physician uses in their practice. They may

work for a laboratory where patients are referred. All of these can create the appearance that the obstetrician-gynecologist is utilizing that facility or medication because of the family relationship. If this is unknown then a conflict of interest may arise.

As I stated earlier, all conflicts of interest are neither bad nor wrong. They just exist and when they occur, the appropriate way to manage them is disclosure. We will investigate disclosure next.

MANAGING CONFLICT OF INTEREST

In order to recommend management of conflict of interest, organizations, and other groups in which obstetricians and gynecologists belong need to establish policies to address the issue. As noted previously, FIGO has developed these policies for their officers and committee members and they can be used as a guide, if no other resources are available.² Many large FIGO member societies have also developed these policies and they are available for their members and most are in the public domain and readily accessible.

A conflict of interest policy should contain a clear statement about all areas of conflict, including any restrictions or limitations that are part of the policy. It should identify when it is applicable and what action should be taken whenever a situation arises. The most common means of addressing a conflict of interest is by public disclosure of the conflict.¹⁶ This should be prior to any presentation or other activity and should be specific about the conflict. It is not acceptable to just state that a conflict of interest has occurred but no details of what has caused a conflict are reported.

For the individual obstetrician-gynecologist, it is important to become familiar with any policy that is applicable to their practice

and practice activities. When possible, avoidance of the situation that could lead to a conflict is preferable. In all cases, avoiding is better than disclosure as it removes the source of the conflict.

Conflict of interest policies should always be transparent and whenever possible support elimination. When this is impossible, careful explanation is required.¹⁷ Disclosure is the usual recommended method of management. All patients have the right to information about all aspects of their healthcare. Patients should always be an integral part of the decision-making process from the initial tests, throughout the entire diagnostic program, when determining the therapeutic course and when initiating the therapy. This includes explanation of the diagnosis and any tests used to establish the diagnosis. Once the diagnosis is established, it includes a discussion of the benefits and risks related to any recommended treatment. It is during all of these discussions that any conflict of interest should be identified and explained to the patient. How extensive this explanation becomes will vary depending upon the extent of the conflict of interest. Fineberg recommends the “reasonable person standard” for how detailed the explanation should be.¹ This is a subjective explanation that assumes a basic knowledge of the conflict but not an intense or deep understanding. It is designed to give the necessary information that can protect the public trust in the physician by informing the patient of any area, which impacts on their care. For example, if a physician is on a company advisory panel for a particular condition or diagnosis where a company medication is recommended, the patient should be aware of this fact as well as made aware of any alternative effective medications.

The fact that there is a need for disclosure does not necessarily imply that the relation-

ship is either bad or wrong. However, the patient needs to be aware of any relationship that exists. The same is true for a presenter at a CME session or any other physician patient/audience interaction. But, how detailed a disclosure should be is often a subject of much debate. In general, using the “reasonable person standard” the obstetrician should explain why there is a conflict of interest and how that affects the action that is being proposed or taken in details that a nonmedical person can understand. Some things are accepted such as the obstetrician-gynecologist is being paid for the visit and subsequent treatment. It is the nonvisit environment where the disclosure becomes most important, as it relates to other financial relationships. Using the reasonable person standard again, the effect of the disclosure is to increase trust and to avoid any concern that the obstetrician-gynecologist is directing care in order to obtain personal benefit rather than for the patients benefit. There is the possibility that disclosure can lead to unintended consequences, such as the patient refusing any care or the most appropriate care; however in most cases, disclosure is better than non-disclosure, especially when the conflict may be later found to have harmed the patient.

Disclosure is also important for researchers and the journals that publish their work. Both legal and informational reasons require all authors to identify any conflict of interest. “Conflict of interest disclosures are critical to the trust and confidence scientists and clinicians want to place in journals and peer-reviewed research.”¹⁸ Without disclosure, potential bias can never be identified.

Unfortunately, disclosure is not always successful. It is only a method for providing information of a potentially biased presentation, but it does not require the patient, reader, or listener to accept that a bias does exist.⁶

CONCLUSION

Conflict of interest does exist in the practice of obstetrics and gynecology and often for the practitioner on a daily basis. It is important to identify and disclose any conflict of interest. "Judgment and integrity are two hallmarks of professionalism. Conflict of interest, bias, and dishonest representation represent a spectrum of threats to judgment and integrity."¹⁷

As noted previously, not all conflicts of interest are bad or wrong. However, the source should be eliminated when risks exceed benefits and otherwise, whenever possible. Physician and patient relationships are based on trust and are essential for successful patient care and maintaining the professionalism of obstetricians-gynecologists. Conflicts of interest have the potential to erode this trust and as a result the professionalism of the specialty. Physician to physician and physician teacher to physician student are likewise based on trust. Conflict of interest has the potential to erode this trust as well. To avoid either of these situations, conflict of interest must be recognized as one of the most important and critical issues facing the obstetrician-gynecologist and the specialty of obstetrics and gynecology today. Conflicts of interest, if they cannot be avoided, should always be disclosed.

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Criminalization of Medical Errors

Sanjay Gupte

INTRODUCTION

Doctors and healthcare providers can be held criminally liable in two types of circumstances. First, criminal liability may arise when healthcare providers violate laws and regulations during their—(1) healthcare business operations (e.g. violating fraud laws, fraud, diverting controlled substances, or falsifying documents) or (2) direct patient care (e.g. extracting sexual favors for health services, performing illegal abortions or euthanasia, or providing substandard care).^{1,2}

Criminal prosecutions for violations during direct patient care are not new, but what may be new is an increasing trend for prosecutors and citizens to take action, a second form of criminal liability.¹ Rising trends in criminal investigation and prosecutions for medical errors related to substandard care began during the 1990s, especially in the United States and United Kingdom. Although such actions remain rare, they have become a real concern, especially in some of the countries.

Prasutr Thawornchaisit and colleagues carried out modified scoping reviews to identify the changing trends in criminal prosecutions in various countries. They found that criminal actions reported from the US and UK may be slightly higher than those reported for physicians in Canada, New Zealand, and Australia, where differences may be due to reporting criteria rather than

criminal propensities.³⁻⁶ They also found that, currently, more Japanese citizens are reporting and filing complaints, which means authorities conduct more criminal investigations. This may be due to less resort to other measures to obtain justice. In Germany, citizens can and do file criminal actions against their physicians for injuries and death related to direct patient care.⁷ One author-reported data from 2008 suggesting at least 3,000 criminal investigations for medical errors are undertaken yearly in Germany. Similarly in Thailand⁸ and in India (Supreme Court), the criminal prosecutions seem to be increasing.

The purposes of this chapter are to describe the reasons that may account for the trend of increasing criminal liability for medical errors, to explain relevant concepts, to assess the ethical dimensions of this trend, and to propose practical remedies to reverse this disturbing trend.

INCREASING TREND TOWARD CRIMINALIZATION OF NEGLIGENCE

Why are criminal prosecutions increasing?

Reasons for increasing trends in criminal prosecutions may be different in different countries but the common threads include—(1) the increased number of adverse events and medical errors occurring within modern healthcare system leading to morbidity and

mortality;^{9,10} (2) diminished confidence in effective self-regulation by healthcare authorities and organizations; (3) wishing to obtain faster justice through criminal, rather than civil, proceedings; (4) reduced awe and respect toward the healthcare providers; and (5) the willingness of prosecutors to tackle these complex issues of medical negligence.

RELEVANT CONCEPTS

Criminalization

The purpose of criminal law is to define socially intolerable conduct and to make specific prohibitions punishable by civil or criminal law.¹¹ Criminalization is a legislative function, which denotes a process of labeling a particular behavior or conduct as criminal,¹² which means that an individual is harmed to such an extent that the community considers itself harmed. A civil offense harms only an individual.

The essential elements of a crime are—(1) intent (*mens rea*) and (2) the act (*actus reus*). To constitute a crime, the act must be volitional and the intent must be to accomplish the criminal purpose.¹¹ To cross the line from civil to criminal negligence, there must be a “gross or flagrant deviation from the standard of care”. In addition, the healthcare provider must also have a criminally culpable state of mind. A healthcare provider charged with criminal medical negligence may not necessarily cause intentional harm. Instead, a negligent state of mind involves a situation in which the provider “should have been aware” of a “substantial and unjustifiable risk” but was not.¹³

Medical Negligence

The essential components of medical negligence, as recognized, are three: (1) “duty”, (2) “breach”, and (3) “resulting damage”, that is to say: (1) the existence of a duty to take care,

which is owed by the defendant to the complainant; (2) the failure to attain that standard of care, prescribed by the law, thereby committing a breach of such duty; and (3) damage, which is both casually connected with such breach and recognized by the law, has been suffered by the complainant. If the claimant satisfies the court on the evidence that these three ingredients have been established, the defendant should be held liable in negligence.¹⁴

Negligence as a Crime

It is claimed that negligence is negligence and jurisprudentially no distinction can be drawn between negligence under civil law and negligence under criminal law. But actually this is not so. There are various differences. In the case of *Andrews v Director of Public Prosecutions 1937*,¹⁵ which stated, “Simple lack of care, which constitutes civil liability, is not enough for the purposes of the criminal law. There are degrees of negligence and a very high degree of negligence is required to be proved before felony is established”. Various courts have accepted this concept that the factor of grossness or degree does assume significance while drawing distinction in negligence actionable in tort and negligence punishable as a crime. To be justifiably regarded as a crime, negligence has to be gross or of a very high degree. Generally speaking, it is the amount of damages incurred, which is determinative of the extent of liability in tort; but in criminal law, it is not the amount of damages but the amount of degree of negligence that is determinative of liability. In practice, it may happen that the patient suffers extensive damage that caused by small degree of negligence, which may not be sufficient for criminal prosecution of the physician. In contrast, the patient may suffer small damage but the negligence may be gross. In this situation, as he has

suffered less damage, he may not like to go far criminal prosecution of the physician because the patient is more grieved by the damage he has suffered rather than the degree of care or lack of it the physician has exercised. The essential ingredient of *mens rea* cannot be excluded from consideration when the charge in a criminal court consists of criminal negligence. Criminal punishment carries a substantial moral overtone. Some of the life's misfortunes are accidents for which nobody is morally responsible. Others are wrong for which responsibility is diffuse. Yet others are instances of culpable conduct and constitute grounds for compensation and at times, punishment. Distinguishing among these various categories requires careful, morally sensitive, and scientifically informed analysis.¹⁶

A doctor is not criminally responsible for a patient's death unless his or her negligence or incompetence went beyond a mere matter of compensation between subjects and showed such disregard for life and safety of others as to amount to a harm not just against the individual patient but to the community. Negligence in such circumstances becomes a crime against the state.

Another difference is that, in a civil case, the fact at issue must be proved by a "preponderance of the evidence". In a criminal case, the state or federal government must prove its case "beyond a reasonable doubt", a much more demanding standard that is designed to protect those innocently accused of a crime. Some legal scholars define preponderance of the evidence as being merely more likely than not, something more than a 50% probability; this is the standard for civil litigation, which includes most malpractice cases. In contrast, when a criminal defendant is tried, the prosecution must prove beyond a reasonable

doubt that a crime was committed and that the defendant committed the crime.¹¹

Culpable State of Mind

A criminally culpable state of mind, that is, *mens rea*, is an element of most criminal acts, including criminal medical negligence. The physician guilty of criminal medical negligence must not only have committed a gross deviation from the standard of care, but must have done so with a criminally culpable state of mind. *Criminal negligence* is the disregard of a substantial and unjustifiable risk of which the defendant *should have been aware*, but was not.¹³ *Criminal recklessness* is the disregard of a substantial and unjustifiable risk of which the defendant *was aware*.¹³ Criminal recklessness requires the defendant to be subjectively at fault. The defendant must have known that he or she was taking a substantial and unjustifiable risk, but consciously ignored the risk and continued the dangerous conduct.¹³ In cases of criminal negligence, the defendant's risk taking is merely inadvertent.¹³ In neither situation does the physician deliberately intend to cause harm to the patient.

Profession versus Occupation

The courts have dealt with how profession differs from an "occupation", especially in the context of performances of duties and hence the occurrence of negligence. In the matter of professional liability, professions differ from occupations for the reason that professions operate in spheres where success cannot be achieved in every case and very often success or failure depends upon factors beyond the professional person's control. A case of occupational negligence is different from one of professional negligence.

ASSESSING CRIMINALIZATION OF NEGLIGENCE

Criminalization Bears the Burden of Justification

No sensible professional would intentionally commit an act or omission, which would result in loss or injury to the patient as the professional reputation of the person, is at stake. A single failure may cost him dearly in his career. Even in civil jurisdictions, the rule of *res ipsa loquitur* (“the thing speaks for itself”) is not of universal application and has to be applied with extreme care and caution to the cases of professional negligence and in particular that of the doctors. Otherwise, it would be counterproductive. Simply because a patient has not favorably responded to a treatment given by a physician or a surgery, the doctor cannot be held liable per se by applying the doctrine of *res ipsa loquitur*.

The Supreme Court of India in a landmark judgment has very lucidly put forward its view. The Court’s reasoning merits quoting it in full:

- A medical practitioner faced with an emergency ordinarily tries his best to redeem the patient out of his suffering. He does not gain anything by acting with negligence or by omitting to do an act. Obviously, therefore, it will be for the complainant to clearly make out a case of negligence before a medical practitioner is charged with or proceeded against criminally. A surgeon with shaky hands under fear of legal action cannot perform a successful operation and a quivering physician cannot administer the end-dose of medicine to his patient. If the hands be trembling with the dangling fear of facing a criminal prosecution in the event of failure for whatever reason—whether attributable to himself or not, neither a surgeon can successfully

wield his life-saving scalpel to perform an essential surgery, nor can a physician successfully administer the life-saving dose of medicine. Discretion being better part of valor, a medical professional would feel better advised to leave a terminal patient to his own fate in the case of emergency where the chance of success may be 10% (or so), rather than taking the risk of making a last ditch effort toward saving the subject and facing a criminal prosecution if his effort fails. Such timidity forced upon a doctor would be a disservice to the society.¹⁷

Labeling a particular behavior as criminal leads to unqualified interference and destructive consequences. This is the reason why when there is a need to regulate conduct, regulation through criminal sanctions bears the burden of justification. The process of labeling a particular conduct as criminal is therefore not a default position. Rather, doing so requires justification, especially in view of the fact that the intrusive character of criminal law disturbs the autonomy and freedom of the individual.¹² Risking such harm to both an individual and the community from a misuse of state power requires stringent justification that the civil law is not an adequate response and that these two serious harms are not likely to occur.

The subject of negligence in the context of medical profession necessarily calls for treatment with a difference. Several relevant considerations in this regard are found mentioned by Alan Merry and Alexander McCall Smith in their work “Errors, Medicine and the Law”.¹⁸ There is a marked tendency to look for a human actor to blame for an untoward event, a tendency that is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. To draw a distinction between the blameworthy and the blameless,

the notion of *mens rea* has to be elaborately understood. An empirical study would reveal that the background to a mishap is frequently far more complex than may generally be assumed. It can be demonstrated that actual blame for the outcome has to be attributed with great caution. For a medical accident or failure, the responsibility may lie with the medical practitioner and equally it may not. The inadequacies and intrinsic limits of the healthcare system, the specific circumstances of the case, the nature of human psychology itself, and sheer chance may have combined to produce a result in which the doctor's contribution is either relatively or completely blameless. The human body and its working are nothing less than a highly complex machine. Coupled with the complexities of medical science, the scope for misimpressions, misgivings, and misplaced allegations against the operator, i.e. the doctor, cannot be ruled out. One may have notions of best or ideal practice, which are different from the reality of how medical practice is carried on or how in real life the doctor functions. The factors of pressing need and limited resources cannot be ruled out from consideration.

Dealing with a case of medical negligence needs a deeper understanding of the practical side of medicine. At least three important considerations can be pointed out, which any forum trying the issue of medical negligence in any jurisdiction must keep in mind. First, legal and disciplinary procedures should be properly founded on firm, moral, and scientific grounds. Second, patients will be better served, if the real causes of harm are properly identified and appropriately acted upon. Third, many incidents involve a contribution from more than one person (team errors) or the healthcare system (system errors) and the tendency is to blame the most identifiable element in the chain of causation, the person holding the "smoking gun". The meaning of

an "accident" during the course of medical or surgical treatment has a wider meaning than such simplistic thinking.

The law laid down by the Privy Council in *John Oni Akerele v. The King* AIR 1943 PC 72. A duly qualified medical practitioner gave his patient an injection of Sobita, which consisted of sodium bismuth tartrate as given in the British Pharmacopoeia. However, what was administered was an overdose of Sobita. The patient died. The doctor was accused of manslaughter, a reckless and negligent act that caused death. He was convicted. The matter reached in appeal before the House of Lords. Their Lordships quashed the conviction. On a review of judicial opinion and an illuminating discussion on the points, what their Lordships reasoned:

- That a doctor is not criminally responsible for a patient's death unless his negligence or incompetence went beyond a mere matter of compensation between subjects and showed such disregard for life and safety of others as to amount to a crime against the State.
- That the degree of negligence required is that it should be gross and that neither a jury nor a court can transform negligence of a lesser degree into gross negligence merely by giving it that appellation. There is a difference in kind between the negligence, which gives a right to compensation and the negligence, which is a crime.
- It is impossible to define culpable or criminal negligence, and it is not possible to make the distinction between actionable negligence and criminal negligence intelligible, except by means of illustrations drawn from actual judicial opinion. The most favorable view of the conduct of an accused medical man has to be taken, for it would be most fatal to the efficiency

of the medical profession if no one could administer medicine without a halter round his neck.¹⁷

Their Lordships refused to accept the view that criminal negligence was proved merely because a number of persons were made gravely ill after receiving an injection of Sobita from the appellant coupled with a finding that a high degree of care was not exercised. Their Lordships also refused to agree with the thought that merely because too strong a mixture was dispensed once and a number of persons were made gravely ill, a criminal degree of negligence was proved.

Negligence in the context of medical profession necessarily calls for a treatment with a difference.

Arguments for and against Prosecuting Medical Professionals

Proponents of criminal prosecution rely on utilitarian and retributive theories of justice to justify their position.

Utilitarians believe public policy should be based on the expectation that the policy will benefit both individuals and society. Criminal sanctions are appropriate when punishing negligent conduct because prosecution encourages all individuals to conduct themselves with more caution.¹⁹ Utilitarian theory applied to healthcare supports the notion that the threat of criminal sanctions would force physicians to monitor their own practices.¹⁹ This would benefit both patients and society by improving the process and outcomes of patient care.

Retributive justice, a theory centered on the notion that punishment is justified on the grounds that the criminal has created an imbalance in the social order, also supports criminal sanctions for medical acts.²⁰ A physician's inadvertent risk taking may be viewed as a "fault in social interaction" that should

be punished through criminal sanctions.²⁰ Hoffmann¹ specifically discusses the goals of deterrence, rehabilitation, and retribution, and analyzes how each of these goals fails to apply in a criminal medical negligence action. Professor Hoffmann argued that criminal prosecution has little deterrent effect because the physician's actions in these negligence cases are not intentional. Additionally, she discussed how criminal prosecution can create an "oppositional culture" and "antideterrent effect" among physicians who may group together and view such prosecutions as illegitimate. She also observed that rehabilitation for physicians in the form of mentoring and retraining is unlikely to be achieved within the criminal justice system. Finally, there is the goal of retribution, or repayment for the offense that was committed. To Professor Hoffmann, retribution for a criminal action is unjustified, if the element of intent is lacking.¹

Those who oppose criminally punishing negligent medical conduct argue that a just criminal system should only punish those who have voluntarily committed a wrong.¹⁹ Based on this theory, it would be unjust to punish an actor for risk taking that is inadvertent or when the actor is unaware that the conduct creates a risk of danger.¹⁹ In addition, a negligent actor who fails to identify his dangerous conduct would also fail to comprehend the potential threat of sanctions for such conduct.²¹ Therefore, it would be unjust for such a defendant to lose his liberty and be stigmatized.²²

These problems illustrate that making medical negligence a criminal offense neither establishes a consistent standard with which to prosecute nor fulfills the objectives of criminal punishment. It follows that medical negligence should remain a civil matter.

Medical associations and physician specialty groups insist that criminal prosecution for clinical errors would set a dangerous

precedent.²³ They argue such a precedent will drive physicians away from taking hard cases or experimenting in new areas.²⁴ Others argue that such a precedent will encourage the practice of defensive medicine and further drive up the cost of healthcare.²⁵ There may come a day when only the bravest or most foolhardy clinician will opt for anything but the least controversial option.²⁶ This will represent regress, not progress, in improving patient safety and quality.

This assessment of the criminalization of negligence is not meant to suggest that doctors can never be prosecuted for an offence of which rashness or negligence is an essential ingredient. This assessment, by contrast, emphasizes the need for care and caution in the interest of society; for, the service which the medical profession renders to human beings is probably the noblest of all, and hence there is a need for protecting doctors from frivolous or unjust prosecutions.

ONE REMEDY

Some health policy challenges require multiple remedies. Not so for criminalization of medical negligence.

Preindictment Screening Panels

Physicians who are charged with criminal medical negligence should be charged only when there is evidence to support both causation and a gross deviation from the standard of care, as well as the requisite state of mind. Accordingly, requiring prosecutors to present their cases to a medical review panel before seeking an indictment would reduce the likelihood of unmeritorious prosecutions for criminal medical negligence.²⁷ Establishing such a requirement by law will protect the criminal justice system and the integrity of the medical profession.²⁸

International Federation of Gynecology and Obstetrics (FIGO) has recently provided guidance:

- Doctors and leaders in the specialty should observe the well-recognized, internationally accepted professional responsibility to enhance patient safety and quality of care, in order to minimize medical errors.
- To achieve this reform, doctors and their professional associations (where they exist) should create and adapt clinical guidelines and standards conduct directives for all their fellow members. At the same time, they should also advocate for the creation of mandatory pretrial review of criminal charges alleging medical error, conducted by government-supported independent peer review committees, whose reports would be available to parties in related criminal proceedings. This pretrial review must involve the doctor concerned.

CONCLUSION

All this discussion does not mean that the healthcare providers should be fully absolved from all their criminal actions. This way the balance of unnecessary harassments of medical professional and justice to the patients will be balanced out. This will help in restoring faith in the health systems and professionals in the future.

The physician must be careful not to exceed his or her expertise, particularly if the work appears to be undertaken more for financial gain than patient welfare. Finally, the physician who fails to follow-up conscientiously on his or her patients or who is caught attempting to cover up a clinical mistake risks being viewed as a physician who should be punished when something goes wrong, regardless of issues of causation and standard of care.

The process of labeling a particular conduct as criminal requires rigorous justification

in view of the fact that the intrusive character of criminal law disturbs the autonomy and freedom of the individual.¹² Criminal negligence should not be equated with civil negligence. On the other hand, a “laissez faire” approach to doctors who have committed negligent conduct should not be adopted. The medical professional bodies should bare the onus of setting standards of practice and helping to implement the same amongst their member community. This restoring confidence in professional self-regulation will become a powerful antidote to criminal prosecutions and loss of confidence in the adequacy of the civil law to respond to most cases of medical negligence.

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Section 4

Ethics Education in Obstetrics and Gynecology

CHAPTERS

**FIGO Introduction to Principles and
Practice of Bioethics**

Bernard M Dickens

Case Studies in Women's Health

Bernard M Dickens



FIGO Introduction to Principles and Practice of Bioethics

Bernard M Dickens

INTRODUCTION: THE CONTEXT

The purpose of the International Federation of Gynecology and Obstetrics (FIGO) bioethics training program is to equip medical students and practitioners of gynecology and obstetrics to understand ethical concerns that arise in women's healthcare, and to resolve these concerns by ethically as well as medically satisfactory means. Ethical sensitivity is based on awareness that, in many social and family settings, women have a different, often subordinate or disadvantaged, status from that held by men. This is associated with the different social and economic functions that women tend to perform, such as caring for newborn and young children, and disabled and elderly members of their families, rather than being engaged at the forefront of social, economic, and political life.

Training in bioethics is required to bring out the best qualities of understanding of, and compassion for, their patients in gynecologists and obstetricians. Training is also required because ethical values increasingly underpin women's human rights entitlements that are expressed in laws. Access to appropriate healthcare is increasingly recognized to be a human right and legal right, of which medical professionals should be aware. Respect for these rights should be incorporated into clinical practice as an aspect of medical professional ethics and skill.

A challenge in bioethical analysis that should precede decision making is for health-care providers to understand the biases and stereotypes that they bring to the task of decision making due to their own characteristics and cultural conditioning. Care and training are required to ensure that women patients are not viewed through assumptions and stereotypes that deny or compromise the human rights to which they are ethically entitled.

Human rights are detailed in legally binding or influential international treaties, national constitutions, and/or national laws and codes, all reflecting contents of the Universal Declaration of Human Rights. This was proclaimed by the General Assembly of the United Nations in 1948. Rights include, for instance, rights to security of the person, to protection against suffering cruel, inhuman or degrading treatment, to found a family, and to nondiscrimination on grounds such as sex, race, color, religion, national or social origin, and birth or other status. Such individual rights are expressions of the first sentence of the Universal Declaration, "All human beings are born free and equal in dignity and rights". Respecting patients' dignity, whatever their circumstances such as income, age, or origins, goes a long way toward satisfying ethical requirements.

A contrast is sometimes drawn between positive and negative rights. Holders of positive rights are entitled to be provided with

means to give effect to such rights, for instance by governmental or other agencies. Most human rights are negative rights, meaning that holders must be free to give effect to their rights by whatever means they can lawfully mobilize. Those who deliberately obstruct others' pursuit of their rights behave unethically, and often illegally. The human right to dignity, however, is both negative and positive. Individuals must be able to pursue this right by their own means, and must also be treated by others, including ethical health-care providers, with respect for their dignity.

BACKGROUND OF BIOETHICS

The term "bioethics" dates back only to the 1960s, but ethics, as a branch of moral philosophy, has ancient roots in many cultural traditions. Ethics may be understood simply as right conduct, and bioethics concerns correct conduct relating to human medical biology. Different reasons have been advanced to explain the origin and growth of bioethics. One concerns the development since the middle of the 20th century of advanced medical technologies affecting, for instance, life-prolonging means that may be applied, or withheld, and means of bypassing infertility by medically assisted human reproduction. Another concerns movements toward greater social equality, movements that resisted medical paternalism, in order to reduce physicians' superior power based on their medical knowledge, by promotion of patients' rights and power of self-determination, or autonomy. Yet another is decline in popular deference to authority, such as that formerly exercised by political, religious, professional, academic, and related institutions.

There are various orientations to bioethical assessment. A contrast is often drawn between an approach that enforces abstract virtues and principles, and another that takes account of practical consequences. An

approach that applies only principles ("Let right be done though the heavens may fall") may cause avoidable harm, while one that aims only at achieving desired results ("The end justifies the means") may be unprincipled and corrode, compromise or subvert key social and professional values. A more recent approach, of particular relevance to gynecology and obstetrics, is to ask how a policy, principle, or option would affect women's well-being ("To ask the woman question"). Many traditional sources of moral or ethical authority, such as religious, legislative, judicial, academic, and professional institutions, have not included women at all, or have not had women in positions of leadership. They have not been informed of, concerned with, or sensitive to women's experiences, preferences or opinions, and have not considered the implications or effects of their policies or actions on women. These authorities have been impoverished by not inviting or accommodating independent women's views, and by not knowing or respecting how women have to resolve competing responsibilities in their lives.

Modern bioethics is conscious of the need to respect individuals' values, including their religious beliefs, but approaches medical decision making as a human function without guidance from any divine or supernatural agency. It is pluralistic in its incorporation of different philosophies, and encourages the principled questioning of options for action rather than requiring unquestioning obedience to any given authority. Account is taken of the likely or possible consequences of available choices of action, weighing medical, psychological, familial, social, economical, and other relevant considerations in balancing choices against each other. Individuals and institutions are held accountable for the intended and incidental consequences of their choices to act, and not to act.

Competing ethical considerations may be balanced in different ways, depending on different priorities. For instance, a physician deciding whether to offer or undertake a procedure liable to affect childbearing should take account of the woman's future childbearing intentions, hopes, and prospects. Women anticipating childbearing and newly married women may be treated differently from postmenopausal women and those satisfied that their families are complete. In the same way that there may be different medical options, there may be different ethical options.

In order to take account of different ethical approaches to clinical care, research in reproductive health, allocation of scarce resources, and, for instance, balancing of competing interests, a small number of core principles have been identified in the field of bioethics. These are not applied in any hierarchy, but must each be assessed to determine which should be given priority over others to decide how selection of choice among treatment options is best made. There are often different ways of behaving ethically, and one's ethical choice in a given case does not show that another person's different choice is necessarily unethical. Bioethical principles can be applied in different priority, so that different choices can be equally justified. They all require, however, that practitioners give each principle due consideration, and be able to justify the priorities by which to decide.

ETHICS PRINCIPLES

The practice of medicine relies on the ability to put together medical findings and facts with evidence-based guidelines and research to craft a strategy for the unique circumstances that each patient faces. This "clinical" strategy often leads to questions about which approach is right, virtuous, or moral and more importantly how to achieve the same level of

skill at practical wisdom and ethical choice in medicine as we have with clinical skills. At the heart of moral dilemmas in medicine are recurrent ethical principles that need to be examined, drawn from a considerable body of literature that guides the healthcare provider. While we could argue from a basis of practical consequences, a basis of proper motives and of discharge of duties, or of ideal personal virtues, the ethically relevant facts need analysis based on principles. These case studies focus on four major principles, namely to respect patients, promote benefit and to avoid or minimize harm, and to act justly.

Respect for Persons: Autonomy and Protection of the Vulnerable

This principle is often phrased around the duty to respect individuals' right to choose which healthcare interventions are acceptable to them. It does not imply that there is a duty to offer healthcare interventions that are not medically sound or indicated just because a patient wants them. That is, autonomy is the right to choose among indicated and reasonably available options, not the right to receive any treatment the patient wants. Autonomy also includes the right to choose to have others involved in decision making, such as family and community members.

Respect for persons is particularly important for women's health,¹ because in some cultures, women are not respected as decision makers. Respect for a person's choices requires the person to have the capacity to make choices. This means that the person possesses—(1) the ability to receive information of, and to understand, the medical choices, and their benefits and harms (often described as informed consent); (2) the ability to consider those benefits and harms in light of their own perceptions and values; and (3) the ability to communicate their questions and their decisions meaningfully

in the healthcare setting. Given the overall status of women worldwide, there are many circumstances that compromise the ethical foundation of autonomy, and therefore present ethical dilemmas. Women are often vulnerable to incapacities, such as when they are illiterate, and care must be taken both to maximize their means of exercising autonomous choice, and to protect them from harm, injustice, and disrespectful treatment when they are disadvantaged and subject to others' choices.

Among the key ethical issues to consider in applying the principle of respect are:

- Whether the woman is free from coercion, pressure, and undue inducement, applied consciously or incidentally by the healthcare provider, in her decision making. A power differential between the health professional and patient or accompanying persons or family member may make it difficult to understand the individual's choices. Is it really her wish or that of others, such as her children, her husband, or someone else, for instance her village elder?²
- What is the capacity to make choices, and who decides when the person appears to have diminished capacity? Waxing and waning consciousness, or a child's or adolescent's level of capacity to choose, raises issues about who can be a substitute decision maker, and whether or not that person will recommend a course that would be true to what the individual might want, rather than express the decision maker's own beliefs or wishes.
- What are the obligations of health professionals to be sure the patient "understands", given the gap between the knowledge base of the clinician and of the patient? Is it truly possible to give adequately informed consent knowing that the variables are so many in clinical

medicine and that not all outcomes can be foreseen? How do we assure that comprehension of language (for instance through interpreters and scaling information to the knowledge level of the patient) and adequate understanding of the consequences of the choice for benefit and harm are present?

- Finally, confidentiality in decision making is a key area for protecting a patient's right to make a choice, but the limit of that duty may be unclear (for example, if a patient's choice will deny the power of self-protection to another person by not revealing his or her HIV-positive status to a spouse or partner). In principle, patients should determine who receives medical information about them, as an aspect of their autonomy.

Benefit and Avoidance of Harm (Beneficence and Nonmaleficence)

As Hippocrates directed, "Be of benefit and do no harm". This represents the clinician's duty to improve the patient's physical and psychological health with a favorable benefit-to-risk ratio. This requires considering prospective advantages of a treatment option, weighing the side effects or consequences that could cause harm, and assessing the advantages for the patient adequately to exceed the disadvantages. The practitioner must ask what clinical needs are present, and how the choice of actions will address them to the benefit (good) of the patient.

Leading commentators on clinical ethics have noted³ that "good" must be understood in light of achieving a goal of medicine, not for instance merely normalizing laboratory values or stopping a bleeding point. This requires answers to the questions: Does the proposed action cure or stabilize disease? Does it stop untimely death or promote

health and prevent disease? Does it provide good quality of life or relief of suffering? Making sure that the goal of treatment is clear allows clinicians to make sure that the benefits and harms of treatment options are properly assessed in judging the ethical issues at hand, and in particular to assure that policies that affect the direct care of women's health are based on best available evidence.

Justice

Justice addresses what entitlements are due to individuals for their health care. The right of individuals to fair and equitable distribution of the benefits and the risks or burdens of available health care (that is—distributive justice) is particularly relevant regarding women's sexual and reproductive rights.⁴

The scope of potential ethical issues involving justice extends far beyond the immediate concerns raised by the one patient in front of us. Justice demands that we consider the formulation of healthcare systems and the extent to which they provide fair access and benefits, particularly for women, who are often shut out of access due to economic, social, or political disadvantages and exclusion.⁵ Justice raises questions about how we distribute scarce resources (such as the HPV vaccine), whether, for example, on a first-come first-served basis, by lottery, based on the greatest health, social, or other need among competing patients, on the greater means to pay, or on some other formulation.

Justice asks if the decision maker might be compromised by a conflict of interest, or for instance by cultural, religious, or other beliefs that do not allow lawful medical means of best serving the woman's needs. Other concerns include whether we feel bound by duties that may conflict with duties to patients alone, for example, for family safety, staff safety, triage that applies scarce resources only to those who are likely to survive, even if those denied

resources will suffer. These kinds of tradeoffs and considerations face health professionals in every form of medicine on a daily basis. Skill at justly weighing such competing interests against others in determining appropriate treatment options in the care of individual patients may be the hardest skill to achieve in medical ethics.

LEVELS OF ANALYSIS

Bioethical assessments can be made at four levels, but the principal level concerns the doctor-patient relationships. This is the *microethical* or person-to-person level. For development of skill in ethical decision making in clinical care, this is where major attention and training are required. Most of the case studies in this training program are pitched at the doctor-patient relationship.

In contrast, the public health, *macroethical* level is concerned with group-to-individual and group-to-group relationships. In-between is the administrative, bureaucratic, or *mesoethical* level, which addresses resource allocation within an institution such as a clinic or hospital, or in a governmental structure such as a village, town, city, local region, or nation. Transcending these levels is the *megaethical* level, sometimes described as global ethics, addressing international and intergovernmental relations and agencies in the healthcare sector.

Decisions that are ethically defensible at one level and might be ethically challenged at another, so practitioners may have to start their analysis by determining its appropriate level. For example, a provider may order an additional test on a generally healthy patient, such as an X-ray, or CT (CAT) scan, out of an abundance of caution in the patient's interest. This may be microethically defensible. However, at the mesoethical and macroethical levels, when supply of the test draws on a group's limited resources of funds, personnel,

and/or access to equipment, it may be criticized as an extravagant use or waste of scarce resources, denying indicated treatment of a sick patient. Similarly, a survey of long-term treatment effects on cervical cancer patients may require review of patients' identifiable medical data. This may be ethically defensible at a macroethical or public health level, but compromise patients' confidentiality at a microethical level.

Ethical challenges arise when a provider is responsible for care of two or more patients whose treatment requires use, for example, of a drug of which the facility has a supply sufficient for only one, or of equipment the use of which for one will deny its timely availability to the other(s). The provider must resolve this conflict of commitment by evaluating one patient's ethical claims over those of the other patient(s). The provider may explore, for instance, whether differences in the patients' medical status affords an ethically relevant distinction that justifies favoring one patient over the other(s). For instance, a decision simply favoring the younger over the older, or vice-versa, or a mother with dependent children over a childless patient or one with adult children, will have to overcome ethical and related human rights claims to nondiscrimination on grounds of age, marital status or number of dependents. The choice is more complex when a patient with no dependent children is caregiver, for instance, to a disabled or elderly relative.

Practitioners with clinical care responsibilities may also be required to serve in administrative positions that involve, for instance, allocation of resources. They may then have to make mesoethical choices that conflict with their microethical duties to provide their own patients with the best possible care, such as on grounds of institutional budgetary discipline, to terminate or restrict availability of expensive drugs or devices their own

patients need for adequate care. Ideally, such conflicts should be avoided by administrators not having clinical responsibilities, but may be unavoidable due to personnel shortages and during transitional periods between clinicians' appointments to managerial roles.

Apparent inconsistencies or contradictions in preferences or policies may be resolved by reference to different levels of analysis. For instance, some who support women's choice to continue or terminate pregnancies without legal control also support laws prohibiting prenatal disclosure of fetal sex. Their purpose is to restrict opportunities for sex-based abortion, perceived to target female fetuses. Those who favor both policies may explain that the abortion decision should in principle be made at the microethical level, between a woman and her doctor (see FIGO Ethics Committee; *Ethical Aspects of Induced Abortion for Non-medical Reasons*, 1998). The decision to prohibit prenatal disclosure of fetal sex, however, is in principle a macroethical decision to be reached at the societal or public level (see FIGO Ethics Committee: *Sex Selection for Non-medical Purposes*, 2005). This is because it may affect women's social status, dignity, and equality with men in their communities. Sex selection, other than for sex-linked genetic disorders or, although controversially, to produce a family with children of both sexes, might also cause social disorder if it causes or aggravates a serious imbalance in a national sex ratio, for instance resulting in a large number of adult men who are unable to find wives. In addition, rejection of sex selection may be of megaethical significance in reinforcing the equal status of women in all cultures and communities, reflecting condemnation of discrimination against girl children and women in international human rights treaties.

CLINICAL CASE ANALYSIS

Having a format in which a clinical case can be analyzed for ethical assessment and decision making is much like separating a clinical presentation, for purposes of informing patients' decision making on medical matters, into symptoms, observations, assessments, and plans. Routine use of one of the case structures for analysis leads to facility in thinking through the ethical dilemmas often encountered in reproductive health in general and women's health in particular. It is important to progress from just discussing hypothetical cases to using cases encountered daily in practice to hone ethics skills, and then to use the hypothetical cases to add background and the comfort of knowing that others have pondered similar cases in the past.

Common to all methods is the need to be sure that the information gathered is accurate, and both medically and patient-based. Additionally, the ethical decision makers involved (including the entire healthcare team) and the possible options and issues need to be brought to the table, including the legal framework where necessary. Finally, an analysis with justification from ethical and social perspectives can be shared before the final options are decided on. In developing ethics consultation services, an additional option of including the patient and her family, when feasible, has been applied successfully in many settings, and may enhance the environment of patient-/woman-centered care in institutions.

Routine use of the 4-box method proposed by Jonsen, Siegler, and Winslade is suggested

for ease of application from the clinician's point of view. This method is philosophically a casuist (i.e. a case-based) approach that assumes there is a clear paradigm case (perhaps more like one of the sample case studies available), and then develops different variations that require discussion and collective analysis. Practically, an easy way is to form four boxes and fill in each sequentially and completely (along with the ethical issues raised in the box) before overall discussion of the case occurs. Often, the "clear" case, for instance of benefit and harm, turns out to be a different case, such as of autonomy or protection against vulnerability, or another principle rather than the one that seemed so clear on initial focus on just one area. A unique set of ethical dilemmas in reproductive and women's health is one in which there is a fetal as well as a maternal issue for consideration, and division of the boxes to represent the issues for both mother and her fetus or child can facilitate thinking.

The four boxes are conceived as—(1) medical indications (including the principles of benefit and harm); (2) patient preferences (autonomy or protection, capacity to choose); (3) quality of life (how does the woman see the intended results of a prospective intervention from her life circumstances, and the impact on her quality of life); (4) context (justice issues). While these are well described in Jonsen, Siegler, and Winslade, the diagram provided below takes into consideration unique aspects of reproductive and women's health (A) and/or fetal/child health (B) that may apply in the individual box (Table 9.1).

Table 9.1: Four boxes for reproductive/women's health.

| | |
|---|--|
| <p><i>1A:</i> <i>Medical indications:</i> Describe the medical circumstances, benefits, and risks of proposed interventions and goals of medicine achieved by intervention. (<i>Examples:</i> HPV vaccine benefit versus risk; C section for obstructed labor; female genital cutting; pain relief for advanced cervical cancer)</p> <p><i>1B:</i> Fetal considerations (for example, death without intervention, significant morbidity with HIV, or prematurity)</p> | <p><i>2A:</i> <i>Patient preferences:</i> Describe what the patient wants (not what her health professionals or her family or her spouse wish, but only what the patient wants), her understanding of the issues, the potential issues of coercion, language, power differential and how they influence authenticity of decision making, issues concerning capacity to choose, and protection of those incapable of choice.</p> <p><i>2B:</i> Consider fetal/child potential wishes as a substitute decision maker: for example, what data exists to understand choices about severe disability, or survival without a mother, if that is the consequence. This may be unknowable.</p> |
| <p><i>3:</i> Quality of life (as defined by the patient, not by the healthcare team). This requires exploration with a patient about what the proposed intervention options will mean to her. (Example: the loss of a child may have great or little meaning for ongoing quality of life; participating in a research study with significant side effects may be chosen because quality of life is defined by the woman by whether or not she is contributing to knowledge for the next woman with her cancer; or side effects may be intolerable because of an impact on her ability to pursue an occupational or leisure activity, such as to knit, weave, read, sing, or play a musical instrument, which defines her quality of life)</p> | <p><i>4A:</i> <i>Justice:</i> Describe issues of distributive justice, economic issues (access, cost), health professionals' concern (their view of quality of life achieved by the therapy), just society issues (treatment of women within the culture), role of religion or other influences on choices</p> <p><i>4B:</i> <i>Fetal/child issues:</i> Cost of care of prematurity and consequent neurological needs, lack of maternal or parental support growing up (if maternal death, HIV-positive status, etc.), paternal or health team issues</p> |

(HPV: Human papillomavirus; HIV: Human immunodeficiency virus)

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Case Studies in Women's Health

Committee on Ethical Aspects of Human Reproduction and Women's Health

Bernard M Dickens

INTRODUCTION

In order to provide students and others with experience of ethical decision making in gynecology and obstetrics, case studies are presented below for analysis. They are based on real-life situations, but facts are usually given in a simple form, so that readers have to address their ethical elements, and not attempt to evade ethical engagement by resort to medical or technical means, or development of additional facts proposed to resolve situations without ethical reflection.

Facts of the cases are followed by some questions, but readers should consider what additional questions are ethically relevant. Background factors are presented in the Assessment sections to place the cases in some of their wider settings, but readers should identify factors from their own circumstances and experiences that they consider ethically relevant. Ethical Analysis sections are then introduced, but not to indicate ethical outcomes or approaches. The purpose is to initiate reflection and criticism in the context of ethical principles, and begin to address applications of relevant principles, perhaps showing contrasts and conflicts that applications may generate. Readers have to work out responses and actions they would propose in each of the cases as being ethically justified and appropriate.

Discussion of ethical elements in cases often shows that there are different ways of acting to resolve them ethically, depending on what factors in cases are claimed to warrant emphasis, what ethical principles are considered to merit priority over others, and the level of analysis of cases seen to be appropriate. Ethically reasoned conclusions that colleagues offer may show that there are different ways to act ethically. That is—differences between reasoned conclusions may not show that, because one is ethical and another that differs is therefore necessarily unethical, but that different types of ethical analysis can result in different ethically justified conclusions. In ethics, unlike, for instance, in some forms of religion, there are no authoritative rulings that command obedience. Individuals must find ethical solutions by themselves, in consultation with others if they wish, and justify them by the processes of ethical reasoning they find most appropriate and most defensible.

Following the Ethical Analysis sections that open consideration of the cases are a few references. These are primarily to the International Federation of Gynecology and Obstetrics (FIGO) Ethics Committee statements and recommendations, which are collected in the FIGO publication entitled “Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Study of Ethical Aspects of

Human Reproduction and Women's Health" (i.e. the Ethics Committee). This FIGO publication is available in English, French, and Spanish, and is accessible online at <http://www.figo.org/about/guidelines>. The print edition is updated every 3 years for the FIGO Congresses.

To supplement these references, students with access to adequate libraries and/or Internet resources will find many relevant articles and commentaries in medical and bioethical journals and other reference materials. These may include, for instance, the British Medical Journal, The Lancet, The New England Journal of Medicine, and similar national and international medical professional journals. Internet access to many journals is free of charge, and other materials may be accessible by university, medical school or other subscriptions of which registered students may avail themselves, as with all such materials, students should be critical of their origins, their liability to (undisclosed) biases, and the contrast between goals of disinterested bioethical analysis, and of ethical advocacy advancing particular interests or perspectives.

ADOLESCENT SEX AND CONFIDENTIALITY

Case

Mila, a 15-year-old girl studying in secondary school, has come to Dr Chidi's office requesting confidential access to contraceptive care. She explains that her poor family cannot afford school fees. For several months, a 50-year-old "sugar daddy" has paid her tuition fees, provided she agreed to have nonprotected sex with him twice a week and does not tell any family member or friend. She is upset and restless day and night, and afraid of becoming pregnant.

Questions

1. Can Dr Chidi ethically provide Mila with contraceptive care, by prescription or otherwise?
2. Is Dr Chidi ethically obliged to respect Mila's request for confidentiality?
3. Does Dr Chidi have any ethical duty or discretion to report Mila's association with the man to her parents, police authorities, or a child protection agency?
4. What advice, if any, should Dr Chidi ethically give Mila apart from regarding contraception?

Assessment

Laws in many if not all countries prohibit sexual intercourse ("sex") with adolescents below a given age, such as 16. Some make an exception if the sexual partner is less than, for instance, 3 years older than the adolescent. Laws that criminalize older partners, such as the 50-year-old man in this case, do not also criminalize the adolescent or make her a delinquent. Accordingly, Dr Chidi would not be facilitating any offence Mila commits by providing her with contraceptive protection.

The human rights of adolescents are declared in the International Convention on the Rights of the Child. This generally applies to every human being under the age of 18, and has been ratified by every country in the world (except Somalia and the USA). The convention recognizes the rights and responsibilities of parents, and to be exercised consistently with "the evolving capacities of the child". In some laws, this is described as the "mature minor" doctrine. This affords adult capacity for certain purposes, particularly receipt of reproductive health services, to legal minors who are sufficiently mature to bear responsibility for their own decisions. Maturity is not age specific, and has to be determined on a

case-by-case basis, specific to a particular adolescent, and a particular decision. When adolescents are mature, meaning that their capacities have sufficiently evolved to be responsible for their decisions, they have the same entitlements as adults, who may at times make poor or imprudent choices. Courts have ruled that minors sufficiently mature to consent to medical treatment by themselves may also decide who may gain information about it. That is their right to decide on medical treatment includes the right to confidentiality.

This means that if Mila is considered mature, she may consent to sex without it being rape. Consensual sex with an adolescent below a legislated age is sometime described as “statutory rape” to distinguish it from nonconsensual sex.

Ethical Analysis

Respect for Persons

Mila is engaging in what is sometimes described as transactional sex, meaning the exchange of material goods or other benefits in return for sex. In some circumstances, especially of deprivation, this has become the norm for adolescent girls, being their main source of income, and paying for their education.

It is evident that Mila would prefer not to have regular sex with the 50-year-old man, but resolved the unfortunate choice between preserving either her sexual integrity or her education in favor of the latter. If Mila is considered mature, she may appear to have made an autonomous decision of what she considered the less bad option, and her choice will warrant respect as well as sympathy. Dr Chidi may find evidence of Mila's maturity in her request for contraceptive protection, and in her discomfort and perhaps suppressed anger that her family's poverty, and her

resulting vulnerability are being exploited. Dr Chidi may accordingly provide contraception.

The ethical principle of respect includes protection of vulnerable persons, and while Mila may have made a mature though reluctant choice to agree to transactional sex, she may appear vulnerable. Dr Chidi cannot protect Mila against her family and social situation, but may provide additional advice, such as against sexually transmitted infections, including HIV, how she may negotiate with the man for safer sex, and how to manage her distress and restlessness.

Benefit and Avoidance of Harm

Since Mila is at risk of unwanted pregnancy, providing an appropriate means of contraception would appear beneficial to her. For benefit to be maximized; however, additional medical assistance and counseling may also be indicated, as addressed above concerning vulnerability.

Because of the extended meaning that may be afforded the concept of violence against women, this case of sexual exploitation of Mila's family poverty, and of the power imbalance between a 15-year-old schoolgirl and a 50-year-old man of financial means may also be helpfully understood as a form of violence. Violence may be seen as a risk factor for the ill-health, physical and/or mental, of women of any age. However, violence against women, of any age and in any form, is to be terminated on discovery whenever possible. A harm to Mila of intervention in this case may be discontinuation of her education, and of all the prospective benefits that education may bring, including her release from poverty.

Justice

A key concept of the ethical principle of justice is that, among autonomous individuals

and to the fullest extent possible involving persons of impaired autonomy, those most affected by decisions should be most influential in making them. Accordingly, Mila should decide who knows about her relationship with the 50-year-old man. If she is a mature minor, she is entitled not only to appropriate medical care, but also to medical confidentiality. Mila may accordingly decide whether her parents, school health authority, or others can have information of her care. This may require Dr Chidi not to be explicit in billing for medical services rendered, in case her parents, school, or others have legitimate access to her medical records. If contraception is given by prescription, Dr Chidi may have to advise Mila how to have it filled with maximum confidentiality.

If Mila is considered not to be mature, she should be afforded due protection, such as by Dr Chidi reporting the circumstances to persons or agencies able to afford Mila protection. Account must be taken, however, of the effect on Mila's education, and of other means she may employ to earn payment of fees in order to remain at school. Further, while the sexual relationship exists, she will require contraceptive and associated protection.

Beyond Dr Chidi's clinical responsibilities are ethical responsibilities at the level of social justice. Access to free education for all children and school-age adolescents correlates highly with indicators of good health. The promotion of a right to accessible education for children and adolescents of all family income levels is an integral part of healthcare at the macroethical level of ethical analysis. Dr Chidi has ethical responsibilities, as an individual and through participation in a professional society, to advocate for a school system to which adolescents will have access without resort to the means MG found she had to employ.

ADOLESCENTS AND FAMILY PLANNING

Case

Patricia, aged 15, is in a sexual relationship with Pablo, aged 19. They intend to marry each other when Patricia is aged 18. They go to their local hospital gynecology department and ask Dr Aye for a family planning method. Patricia is liable to epilepsy and has been taking Phenytoin for the last 7 years, making her ineligible to take a low-dose oral contraceptive or a combined injectable contraceptive method. Dr Aye advises Patricia to consider use of a copper intrauterine device (IUD) and advises the couple on condom use to prevent sexually transmitted infections (STIs).

Local law prohibits any sexual intercourse by those aged under 14 years, and under 16 years except with partners less than 3 years older.

Questions

1. Can Dr Aye ethically advise this couple on contraceptive means they can use?
2. Can Dr Aye ethically fit Patricia with an IUD?
3. Does Dr Aye have an ethical duty to advise Patricia's parents of any proposed contraception?
4. Can Dr Aye ethically bill Patricia's parents for services?

Assessment

Because of Patricia's treatment to control epilepsy, common means of self-administered contraception are contraindicated for her. Insertion of an IUD requires the attention of a gynecologist, and her education on its maintenance. Protection against STIs is important, since two-thirds of all STIs occur

among persons under 25 years of age, and one quarter among teenagers.

Laws against sexual intercourse with minors and adolescents are intended for their protection. Accordingly, while their older sexual partners may commit offences, they do not, since they are regarded as victims rather than as perpetrators of, or conspirators in, such offences.

Ethical Analysis

Respect for Persons

If Dr Aye finds responding to these requests for assistance objectionable, Patricia and Pablo should be referred to another physician who will care for them. Dr Aye's protection of Patricia against unwanted pregnancy by medically appropriate means serves her interests in autonomy. However, Pablo is not legally free to engage in sexual intercourse with her, on account of his age and her perceived vulnerability. He is entitled to receive advice on means to prevent causing unwanted pregnancy, and on means to avoid contracting and transmitting STIs.

If Patricia is mature in her capacity for medical decision making, she is entitled, as a mature minor, not only to accept medical care for her protection but also to decide with whom that information may be shared. Dr Aye may accordingly respect her decision on whether her parents are brought into or advised of her medical treatment decisions. If Pablo's intercourse with Patricia is unlawful, it cannot be remedied by her parents' consent. If she is a mature minor, Patricia can decide whether she requires her parents' protection against any legal offence Pablo may commit.

Benefit and Avoidance of Harm

Protection of Patricia against unwanted pregnancy and STIs is of benefit to her. Advising Pablo of his liability to commit a legal offence

by having intercourse with her before she reaches 16 years of age is beneficial to him, and to Patricia, if she wants to safeguard him against committing any (further) offences. Dr Aye cannot provide Pablo with advice on having safe intercourse with Patricia, since this may appear to be aiding and abetting an offence, but may provide him with non-specific advice on contraception and STI protection of, and from, any sexual partner.

Justice

How Dr Aye is remunerated for services to Patricia and Pablo may raise ethical concerns of justice. If services are billed to Patricia's parents or health insurer, information may be required of the service rendered. To preserve confidentiality, however, this may have to be generalized, such as for gynecological care, not specific to contraception. Further, any such billing cannot cover consultation with Pablo. If care for both Patricia and Pablo is covered by public funds, it must be for separate services to each, since public funds cannot ethically be applied for safety in a joint act or acts in breach of the law. Law is often described as providing a "minimum ethic", because ethical conduct often requires more than simple conformity to the law. That is—ethics may require that individuals do more than just meet their legal responsibilities. However, this also means that it is usually unethical to act, or to facilitate action, in breach of the law.

ANENCEPHALY AND LATE-TERM ABORTION

Case

Ana is the 33-year-old mother of children aged 11, 8, and 6. She lives in a low-income family with her 37-year-old husband and works occasionally in a car wash, while her husband has part-time employment as a

driver. The IUD Ana used for contraception was spontaneously expelled, and now she is 23 weeks pregnant. An ultrasound examination at the government-funded community clinic has diagnosed an anencephalic fetus. Local law allows induced abortion on grounds of a woman's physical or mental health, limited to 20 weeks' gestation except in exceptional circumstances. Dr Gomez, attending Ana at the clinic, told Ana about the risk of stillbirth of an anencephalic fetus, and the strong likelihood of a baby's early death on live birth. Ana was also informed that the clinic and Dr Gomez disfavor abortion, and that, because anencephaly is not of genetic origin, organs from her child following death might be recovered for transplantation to assist sick children's survival. Ana and her husband ask for immediate termination of the pregnancy.

Questions

1. Are there ethical grounds for Dr Gomez to terminate the pregnancy?
2. Is the possibility of organ recovery for transplantation at the baby's death a ground to refuse abortion?
3. What are the ethical responsibilities of Dr Gomez, if refusing abortion on grounds of conscientious objection?
4. What are Dr Gomez's ethical responsibilities, if the clinic is not equipped to undertake a late-term (post-20 weeks' gestation) abortion?
5. Are the interests of Ana's young children of any ethical significance in responding to her request?

Assessment

The incidence of anencephaly is uncertain in countries with prenatal diagnosis and accommodating abortion laws, because diagnosed cases often result in abortion. The condition is assessed to occur in about 1

per 1,000 live births in the USA, and 6–8 per 1,000 for instance in parts of the UK. The incidence among live births is higher where abortion is legally restricted, such as in Latin America. Anencephaly is the most severe fetal neural tube defect, resulting from failure of the neural tube to close at the base of the skull in the 3rd or 4th week after conception. The brain therefore lacks part or all of the cerebrum, and brain tissue is often exposed to injury from amniotic fluid. Stillbirth is the outcome in about 65% of cases, and children born alive are nonviable, usually dying within a few days if not hours. The etiology of anencephaly is unknown, but data suggest origins in poor diet, especially folic acid deficiency. Anencephaly is associated with risks, if dysfunctional labor and complicated delivery, and stressful newborn care until death.

Ethical Analysis

Respect for Persons

Ana's autonomy may entitle her to abortion, if she is considered an exceptional case allowed by the law. The general limit of abortion at 20 weeks' gestation balances health risks to women against fetal interests in survival, but anencephalic fetuses, even if born alive, are not viable. Dr Gomez has autonomy to decline to participate in abortion, but then has to consider referral to a nonobjecting suitable practitioner. Referral is not participation and does not attract the protection of conscientious objection. The clinic administrators similarly cannot invoke conscientious objection, since administration is not direct participation in procedures administered. However, the clinic's inability to undertake a late-term abortion raises the issue of whether transfer to an adequately equipped clinic is ethically required.

Benefit and Avoidance of Harm

The fetus would not be harmed by abortion, since, lacking a functioning cerebrum, it is incapable of consciousness and experience of pain. Its brain stem may support reflex action such as breathing and occasionally responses to sound or touch, but it is not viable or treatable. Dr Gomez might be harmed if compelled to perform an abortion, contrary to the doctor's conscientious convictions. Sparing Ana the experience of delivering a stillborn or dying baby would be beneficial, but there might also be benefit to any sick child that might survive, if transplanted with an organ from Ana's deceased baby. It is uncertain, however, whether determination of the baby's death would be in sufficient time for removed organs to be suitable for transplantation.

Justice

Ana and Dr Gomez are equally entitled to protection of their dignity. In its 2005 decision in the case of *KL v. Peru*, the UN Human Rights Committee found that the state had committed multiple violations of the International Covenant on Civil and Political Rights when state agents obstructed lawful abortion requested by a young woman pregnant with an anencephalic fetus. Compelling her to deliver and breastfeed the newborn dying baby unjustly caused her to suffer deep depression, and was found to constitute cruel, inhuman, and degrading treatment. Compelling Dr Gomez to perform abortion in violation of conscience may similarly be degrading to the doctor. Encouraging Ana to continue gestation to its natural end may spare her the intrusiveness of late-term abortion, and provide her with an opportunity for altruism through organ donation, whether or not any child could receive organs transplanted from the anencephalic baby following its death.

ANTENATAL CARE

Case

Francesca is pregnant for the third time. She has two healthy young children, a boy and a girl, after normal pregnancies. She is now 41-year-old, married, and works as a hospital nurse. During this third pregnancy, she experienced slight genital bleeding at 10 weeks, but had no further bleeding. She feared a miscarriage, but her physician was reassuring, since the clinical examination was normal, the uterine cervix was closed. However, at 20 weeks, a routine ultrasound examination identified several fetal anomalies: a severe cardiac malformation, bilateral club foot, and short-nasal bones. Her physician told Francesca that these malformations were usually indicative of a risk of Down's syndrome, trisomy 21, a chromosomal abnormality due to an extra chromosome 21. Francesca knows by professional experience that fetal trisomy can be identified from a sample of fluid from amniocentesis, after culture of the fetal cells in the amniotic fluid. However, her physician denies Francesca access to amniocentesis, because the country's law prohibits termination of pregnancy based on fetal malformation. The physician explains that prenatal diagnosis of fetal anomaly would be of no benefit to her, and that investigations will be performed only after birth of the baby. The physician adds that cardiac malformation is probably not curable by surgery. Francesca knows that Down's syndrome entails hazards of mental retardation and, in addition to the heart disease, a variety of possible somatic illnesses such as leukemia. Francesca, deeply concerned by the severity of the cardiac malformation and its poor prognosis, and the foreseeable ordeal to the future child's life and to her family, insists that her physician should provide termination of the pregnancy.

Questions

1. Can the physician ethically comply with Francesca's request?
2. Can the physician ethically terminate the pregnancy on grounds of harm to Francesca's physical or mental health, if the law allows these grounds?
3. Can the physician ethically take into account harm to Francesca's young children from birth of a severely handicapped newborn?
4. Is it ethical to deny antenatal diagnosis when a fetus is liable to be severely malformed and incurable before or after birth?

Assessment

The risk of Down's syndrome increases with maternal age above 35 years. After 41 years, it is estimated to affect 1-2% of fetuses. Screening for Down's syndrome is optimally performed, for all pregnant women who consent, during the first trimester of pregnancy, between 11 weeks and 14 weeks. A second trimester ultrasound examination may identify fetal malformations, including cardiac malformation and duodenal atresia, which suggest Down's syndrome. It is then recommended to conduct amniocentesis, and, on proof of Down's syndrome, to discuss termination of pregnancy with the pregnant woman.

Legislation for medical termination of pregnancy varies among countries. In some, it is allowed for a severe fetal disease or malformation until the end of pregnancy. In others, termination is allowed only until 28, 24, or fewer weeks. In some countries where termination is generally forbidden, it is allowed when the woman's life or health is at serious risk.

In all countries, it is prohibited actively to induce death of a neonate (neonatal euthanasia), even for a severely malformed baby. Further, neither antenatal diagnosis nor

termination of pregnancy may be imposed on a woman who does not give her free and informed consent.

Ethical Analysis

Respect for the Person

In principle, personal autonomy requires that a woman should be free to decide whether she is willing or not to give birth to a severely malformed, heavily handicapped, incurable child. If she wishes, she may decide in consultation with her partner and/or family members. She may opt for termination of pregnancy for two related reasons: (1) she does not want her child to suffer the ordeal of unbearable life, and (2) she does not herself feel emotionally strong enough to cope with her child's handicap, and perhaps, its effects on her family. In many countries, however, women's autonomy is denied by laws of different levels of restriction.

Benefit and Avoidance of Harm

The principle of benefit to the born child requires balancing the benefit of birth against the harm of a future life that may be inordinately painful and distressing. However, less impaired children who survive with Down syndrome can enjoy years of comfort, and be a source of pleasure and companionship to others.

Justice

Where medical termination of pregnancy is illegal, the physician has an ethical obligation to obey the law. The physician also has an ethical obligation to counsel and support patients and their families. Some physicians stretch the boundaries of laws that prohibit medical termination of pregnancy, privileging their ethical duty over their strict legal obligation. Others may advise patients that

treatment unlawful at home may be accessible within the law abroad. The duty is to obey the law, not necessarily to respect it. Physicians have the ethical right, and perhaps duty, to urge reform of oppressive laws that cause harm to patients' health, particularly that of vulnerable women.

BIOETHICS AND FAITH-BASED ORGANIZATIONS

Case

Doctors who work in the Department of Obstetrics and Gynecology at City Hospital, chaired by Dr Civis, have been informed that they will receive necessary government subsidies for patients' care and research support only if they create a committee to review their practices and research proposals according to modern standards of bioethics. City Hospital serves an urban population of mixed races and religions, with a relatively high rate of maternal mortality and morbidity, and of infertility, and is organized and maintained by a religious foundation. The Hospital Chief Executive Officer asks Dr Civis to ensure that a majority of committee members will be strictly observant followers of the religion to which the hospital foundation adheres, in order to comply with the foundation's religious values.

Questions

1. Can Dr Civis comply with this request?
2. Can Dr Civis comply, if the religion excludes women from holding influential rank in the religion's authoritative hierarchy?
3. Must Dr Civis ensure the committee's independence?

Assessment

Healthcare facilities founded by religious institutions are entitled to maximize obser-

vance within them of the religious values the institutions uphold and promote. Bioethics is a pluralistic discipline, however, and secular in that it does not incorporate any supra-natural belief system. It applies evidence-based rather than faith-based practices and policies, and its values are related to human rights rather than to religious convictions. Its methodology is based on analytical questioning of claims of correct conduct rather than on obedience to hierarchical authority.

The important bioethical principle of respecting persons requires that individuals be treated with sensitivity to their religious faiths, and that they need not be required to act, or to suffer acts of others, that offend their religious convictions. The Constitutional Court of Colombia has held, however, that institutions such as hospitals cannot invoke conscientious objection to lawful medical procedures on their own behalf, because the human rights to freedom of conscience and of religion are available only to human beings, not legal corporations.

Ethical Analysis

Respect for Persons

The autonomy of persons capable to make their own decisions requires that their own religious preferences be respected, and that they not be compelled to be governed by religious values they do not share. Accordingly, they should be facilitated to obtain lawful healthcare procedures appropriate for them, despite adherents to some religions finding the procedures unacceptable, and to decline procedures to which they object, despite others finding them acceptable. Further, physicians should inform their patients about lawful procedures medically indicated for their circumstances, even if the physicians decline to undertake them on grounds of conscience, and be referred by their physicians or

by others on their behalf to reasonably accessible providers able and willing to undertake such procedures.

Because of their dependency, patients seeking care are vulnerable to subjugation of their own preferences by those who possess the power of relevant medical or other knowledge. It is an unethical abuse of such power if patients are compelled to receive care that offends their religious values, or if they are denied information and/or care relevant to their circumstances because the care offends the values of the healthcare institutions or personnel that profess to serve them.

Benefit and Avoidance of Harm

It is beneficial that institutions be able to function consistently with the religious or other values that inspire them, but harmful, if they induce pluralistic populations to rely on them for healthcare or other services but deny lawful health services that they object to deliver because of their religious beliefs. It is also deceptive, if, under the guise of functioning according to bioethical standards, they practice according only to religious beliefs. If the population that City Hospital serves has alternative access to other hospitals, physicians in the Department of Obstetrics and Gynecology may refer patients to them for services that it would offend the hospital foundation's religious values to deliver. If patients have reasonable access, including affordable access, to alternative facilities, Dr Civis may therefore ethically comply with the request regarding the bioethics committee's composition, by publicizing where patients may obtain services the hospital will not deliver. Otherwise, a choice must be made between acceptance of governmental support and delivery of services according to the pluralistic standards of bioethics, or maintaining religious values but forgoing governmental subsidy and support, and tolerating the harm

of failing to relieve high rates of maternal death and morbidity, and of infertility.

Justice

Reproductive health in general and obstetrics and gynecology in particular centrally focus on women's health. Ethical rules distinguishing proper from improper practices in these areas should be informed by their impact on women, and by women's perceptions and experiences. It is questionable whether rules principally affecting women's health developed by institutions that do not include women in their senior ranks of influence can be ethically authoritative. Many religions have unchanged histories of women's subordination, exclusion, and passivity, which their women followers find it too challenging to mitigate.

Justice requires that members of ethics review committees act independently of other authorities, and assessing the relevance and priority of bioethical principles free from others' direction, although open to persuasion by others whose explanations they find ethically compelling. They have an unacceptable conflict of interest, if they cater their reasoning and conclusions to find favor with religious or other authorities outside the committee, or fear spiritual sanctions if such authorities may find their independent conclusions scandalous or heretical. The power to challenge and contradict others, however high their authority, is characteristic of, and indispensable to the nature of, modern bioethical discourse. Bioethical judgments may, of course, be informed by religious values, but cannot be required to be obedient to religious perceptions or doctrines.

CESAREAN SECTION ON REQUEST

Case

Natalia, 37-year-old, is pregnant for the first time. She works as an executive manager for

a prominent publishing company. She is in good health but, after nearly 2 years of marriage without a desired pregnancy, she needed a mild treatment for ovulation induction in order to become pregnant. The follow-up of her pregnancy was uneventful. She knows by ultrasound that the baby is a boy. At 34 weeks, 7½ months, she discusses with her obstetrician the mode of delivery. Natalia wants to deliver by cesarean section. She argues that, at 37 years of age and with her demanding professional position, she may not have another child. She was the only child of her own family. She has waited so long for this precious baby that she does not want any harm occurring to him during labor or delivery. Above all, she confesses she is rather vain about her appearance and bodily integrity. She fears to suffer a future organ prolapse and urinary incontinence. She does not mind bearing a suprapubic transverse scar, eventually removable with cosmetic surgery.

Questions

1. Should Natalia's obstetrician comply with her request for cesarean delivery?
2. What are the obstetrician's ethical duties to Natalia, if her request is not granted?
3. Would it make an ethical difference, if the procedure was funded under a public or a private health insurance plan?

Assessment

There is an increasing trend toward cesarean sections on request, for maternal preference, without any compelling medical indication. For instance, 31% of female obstetricians in the UK would request a cesarean section when they are pregnant, for the delivery of an uncomplicated singleton cephalic presentation at term. Their arguments are the fear of perineal damage from vaginal delivery, the fear of long-term sequelae such as urinary

stress incontinence and/or anal sphincter damage, the fear of long-term effect on sexual function, and the fear of damage to the baby. Regarding obstetricians' attitudes in Europe to accept a woman's request and perform a cesarean section on demand, the lowest compliance of physicians is in Spain (14%), France (19%), and the Netherlands (22%), the highest is in Germany (75%) and the UK (79%).

However, both obstetricians and patients must be informed that, for an uncomplicated singleton pregnancy at term, the hazards of maternal mortality and of serious morbidity, i.e. pulmonary embolism, is three times higher after a cesarean section than after a vaginal delivery. In addition, for the neonate, the risk of respiratory disease or other neonatal complication may be 40 times higher after cesarean section compared to vaginal birth. Moreover, for the mother, a cesarean section does not guarantee against perineal damage. Urinary stress incontinence and genital organ prolapse are in part due to the pregnancy itself, and the physiological relaxation of the perineal tissues, and are therefore unavoidable.

Ethical Analysis

Respect for Persons

The principle of autonomy provides that an individual is able to decide what is best for him-/her-self, including in the management of medical care, and is free to decide, if a proposed treatment or strategy is acceptable or not. Any individual is entitled to refuse a surgical procedure proposed by a physician.

It does not mean, however, that an individual is entitled to impose a surgical procedure, such as a cesarean section, upon an obstetrician who is reluctant to perform it on request.

Benefit and Avoidance of Harm

Any time a cesarean section is medically indicated, either for a maternal or a fetal condition, the benefit of the procedure surpasses its potential harm, and it is therefore ethically justified. Conversely, if a physician considers that the risk of a nonmedically indicated cesarean section outweighs its benefits, the physician is ethically justified to refuse to perform it, in the name of conscientious objection. The physician then has a moral obligation to refer the patient to another obstetrician known usually to comply with such a request. A much wanted and precious baby is not in itself an indication for a cesarean section, unless some are considered more precious than others, which would be ethically unacceptable.

Justice

If Natalia intends to pay for the procedure from her own resources, it may appear comparable to cosmetic surgery, available as luxury medicine for those with the means and wish to avail themselves of the service. If management of her pregnancy is through publicly funded facilities, however, accommodation of her preference for cesarean delivery that is not medically indicated may make services unavailable or delayed for others in medical need, such as in emergency. Accordingly, her obstetrician and perhaps others responsible for the allocation of hospital or clinical resources will have to assess whether granting Natalia's wish for surgical delivery can be justified. Even if she is covering the costs from her own resources, the concern may arise of whether this deprives those dependent on the public provision of healthcare services of timely and skilled treatment. This points to a macroethical concern of the balance and interaction between concurrent public sector and private sector health services, especially

when physicians work in both systems at the same time.

CHOICE OF HOME BIRTH

Case

Marta, aged 28, gave birth to her two children, now aged 5 and 2, at the nearest hospital, 40 km from her rural home, attended by the semiretired-resident obstetrician, Dr Tien. Both births were relatively normal, the second with a few minor complications. Marta is now 6-month pregnant, with only a distant family history of twin births, and has asked if Dr Tien can attend her delivery at home. She explains that her husband works long hours away from home, and she does not want to leave her two young children without proper care. Further, she finds that the family cannot afford the payment that hospital delivery and care would require. Dr Tien lives near the hospital, and cannot easily travel 30 or more minutes to and from Marta's home.

Questions

1. Can Dr Tien ethically advise Marta that home birth is not as safe as hospital birth, and that she should find means to deliver in the hospital?
2. Should Dr Tien ethically seek means to attend Marta's delivery at her home?
3. Can Dr Tien ethically advise Marta to seek the care of a midwife or other adequately trained person such as a nurse to attend her delivery at home?

Assessment

In many parts of the world, women have no choice but to give birth at home. Where women have a choice, high-risk births are clearly better managed where necessary resources are available. For low-risk and normal births, a 1996 report by a WHO technical

Working Group of the Department of Reproductive Health and Research found generally inconclusive data on the relative safety of health facility in contrast to managed home births. It has accordingly not been shown that home births present greater risks to women and/or infants than hospital births. Homes may not be as free from infection as sterile hospital settings, but hospital-born (nosocomial) infections do occur, as may errors, for instance of babies' identification, that home birth eliminates. In 2010, the European Court of Human Rights drew on this report to rule that a law interfering with physician's participation in women's choice of planned home births violates women's human rights to respect for their private lives.

Ethical Analysis

Respect for Persons

Dr Tien's compliance with Marta's request would serve her autonomy, but Dr Tien is an independent practitioner and has no duty to comply with her request unless a preexisting agreement has been made. Marta will remain autonomous to give birth at home without an obstetrician's attendance. She is vulnerable without adequate skilled assistance, however. Dr Tien may therefore advise Marta on access to appropriately skilled aid, such as from a midwife or trained nurse who can manage home delivery, and ensure transport to a hospital in the event of complications that cannot be adequately resolved at her home.

Benefit and Avoidance of Harm

Whether or not Dr Tien attends the home birth, attention should be paid to the guidance provided in the WHO report. This requires that preparation should be as comprehensive as circumstances allow, with a clean, adequate, warm space for delivery, clean water, careful handwashing, and warm

clothes or towels to wrap around the baby. A suitable delivery kit is recommended by the WHO report to maintain cleanliness and sterility and give adequate treatment to the umbilical cord. Further, without causing Marta undue anxiety or appearing to try to persuade her to opt for hospital delivery, she should be informed that women at high risk of birth complications may not feel ill or show signs of distress and that means of medical intervention in case of emergency concerning the mother and/or baby should be reviewed.

Justice

Although the European Court of Human Rights has recognized women's privacy right to choose to give birth at home, the right, like many human rights, is probably a negative rather than a positive right. That is, although a state's laws may not interfere with physicians' and others' attendance at home births, there is no duty on anyone to facilitate them. States do have duties to provide for safe motherhood and to have adequate hospital, clinical, and related facilities and trained personnel available for this purpose, but they do not necessarily have to provide care for every home birth when women can access such facilities. Accordingly, Dr Tien has no ethical duty to attend Marta's home birth, but has the choice to do so. Whether or not Dr Tien should choose to comply with Marta's request, or alternatively to advise or ensure that she has a midwife's or other suitable attendance, with backup access to the hospital in case of unexpected maternal and/or neonatal complications, is a matter of Dr Tien's ethical judgment.

CLINICAL RESEARCH

Case

Dr Curio is a sole general practitioner in a tropical area some distance away from any

major city. An overseas pharmaceutical company has contacted Dr Curio to enquire whether the doctor would participate in a research study to test a new drug intended to improve treatment of a tropical disease common in the area where the doctor practices. Dr Curio's tasks would be to recruit a number of patients as research subjects, monitor their reactions to the experimental treatment, and report findings to the appointed research administrator. Dr Curio could select in return either a financial payment or a free supply of company products, based on the number of patients recruited.

Questions

1. Can the doctor ethically recruit the doctor's own patients as subjects of this research study?
2. Would Dr Curio be in a conflict of interest by accepting financial payment for entering patients in the study?
3. Would acceptance of free pharmaceutical products for patients ethically justify Dr Curio's participation in the study?
4. Would Dr Curio's participation in the study entitle the doctor to co-authorship of the study's published results?

Assessment

Research reverses the traditional doctor-patient relationship. In that relationship, the doctor serves the needs of the patient; whereas in research, the research subject serves the needs of the investigator. When a doctor becomes an investigator and the doctor's own patient becomes a subject of research, it may not be clear to the patient or to the doctor that their relationship is different and reversed. The requirements of the patient/subject's informed consent are also different, in that a potential research subject must be informed that a proposed new treatment

is unproven, with undetermined risks and side effects, and that there is the choice of having the therapeutic treatment that is usually recommended. Further, although research subjects have been expected to act altruistically, there is growing ethical discussion of whether, unlike patients, they may or should receive financial payment. It is expected that research subjects should receive care for their medical needs without payment, including care for conditions separate from those for which they serve as research subjects. In some circumstances, such as when research subjects come from environments deprived of health services, it may be ethically required that the general healthcare needs of research subjects be met.

Ethical Analysis

Respect for Persons

Respect for patients requires that Dr Curio should inform patients of any proposal to treat them not according to the doctor's disinterested view of their best interests, but according to the requirements of a research protocol. Respect also requires that the doctor takes active steps to disabuse them of the "therapeutic misconception" to which they are liable to be prone, namely, that any form of treatment the doctor proposes is intended primarily for, and likely to achieve, their benefit.

As patients, they are vulnerable to Dr Curio's suggestion of what treatment they should receive. There is not necessarily a contradiction between Dr Curio's recommendation that patients should receive the study drug and the doctor's genuine conviction that such treatment is in the patients' best interests, depending on the therapeutic options available to patients. However, patients may lack access to an independent opinion of where their best interests lie, and lack means

independently to assess whether Dr Curio's disclosure of benefits derived from the doctor's and their own participation in the study resolves any conflict of interest that may affect the doctor's recommendation.

Benefit and Avoidance of Harm

Independent ethics review of a clinical research proposal should assess whether it offers a sufficiently favorable therapeutic or other benefit to justify its risks. If it does, it must still be determined to what or whom the benefit relates, and who bears the risks. The risk bearer is usually the research subject, who may be a patient coming to the doctor for care. If the study promises to benefit this and/or other patients proportionately to the risks that informed patients are competent to accept, it can be considered therapeutically or otherwise beneficial.

The benefits the study offers to Dr Curio are financial payments or free pharmaceutical products. If the doctor applies money income to subsidize treatment of poor patients, or makes indicated drugs available to patients without charge, this may be considered beneficial. If, however, payment goes to the doctor's personal enrichment, or the doctor sells pharmaceutical gifts for profit, patients may not benefit if they accept the risks of an unproven (although not necessarily harmful) treatment.

Justice

Concern regarding justice arises from the power imbalance between doctors and their patients. A doctor often has considerable authority over the patient's access to appropriate care, and sick patients dependent on their doctors for treatment may feel unable to act contrary to their doctors' expressed or implied preferences. The initial ethical understanding is that doctors should

not seek to recruit their own patients as subjects of research, because patients may feel obliged to comply with their doctors' requests or suggestions. Doctors should not request favors from their dependent patients. However, doctors have to pursue their patients' best interests, and Dr Curio may feel in good faith that patients would be better served by entering the study because of the benefits to them. The benefits Dr Curio may derive may have to be disclosed, but this may create pressure that patients feel not to deny the doctor such benefits by declining the doctor's request to take the new product and asking instead for the usual, nonexperimental treatment. Dr Curio's patients may not have access to independent advice when offered a choice between usual and alternative, experimental, treatment.

CONFLICT OF INTEREST

Case

Dr Medico owns the two-storey building near the town center where his busy gynecological practice is located on the upper floor. The street-level floor is rented including to a pharmacy business of which Dr Medico is a 40% proprietor. The business employs three pharmacists and is open 24 hours a day, returning a sizeable profit.

Dr Medico writes many prescriptions for drugs, and advises patients on nonprescription products and devices they may use. Many of his patients take their prescriptions to the ground floor pharmacy to be dispensed. Dr Medico does not inform his patients of his interest in the pharmacy, unless they ask for his recommendation.

When an officer of the medical licensing authority asked Dr Medico about his interest in the pharmacy, he said that it is primarily to ensure the quality and convenience of its services and that its pricing policies are

sensitive to the local community's income level. He also explained that he does not inform patients of his interest in the pharmacy, unless they ask for a recommendation, in case they see this as requiring them to use this pharmacy rather than others.

Questions

1. Should doctors be allowed to have financial interests in dispensing pharmacies?
2. Should doctors be allowed to rent premises near their offices to dispensing pharmacies?
3. Should Dr Medico volunteer information to all his patients of his influence over the ground floor pharmacy?
4. Should Dr Medico be allowed to inform patients who ask for his recommendation about his influence over and financial interest in the ground floor pharmacy?
5. Should doctors who are not prohibited seek the approval of their licensing authorities and/or professional associations before they take financial interests in, or rent space to, dispensing pharmacies?

Assessment

Studies have shown that doctors with financial interests in pharmacies and clinical laboratories write more prescriptions and order more tests per 100 patients than those without such interests. Some medical licensing authorities prohibit doctors from having financial interests in pharmacies and/or clinical laboratories and from renting space to them near their own offices, as constituting a conflict of interest. Studies also show that some pharmacies lacking medical supervision have higher rates of dispensing errors than those that are under medical supervision.

Ethical Analysis

Respect for Persons

Dr Medico's patients retain autonomy to have their prescriptions dispensed wherever they want. Those who use the ground floor pharmacy do not know that their prescriptions and other purchases may benefit Dr Medico. Some might prefer to take their prescriptions to a pharmacy under his influence, if they are confident that proper standards of dispensing will be maintained. Patients uncertain where to go who request Dr Medico's recommendation, will be told of his influence over the ground floor pharmacy.

Benefit and Avoidance of Harm

Some patients may find it convenient to use the ground floor pharmacy, if they live nearby. Those living further away may prefer to use pharmacies closer to their homes. Dr Medico applies no pressure or influence over patients' choices, but assists those who request advice.

Justice

Patients are treated equally in that Dr Medico does not volunteer information of his interest in the pharmacy. Only those who request a recommendation for a reliable pharmacy will be informed. Uninformed patients may go elsewhere, chancing that the services they receive are less reliable. Dr Medico does not distort fair competition among pharmacies by directing his patients to the ground floor business.

COST CONTAINMENT

Case

Dr Techno, on the medical staff of City Center Hospital, is concerned about Rosa, a 27-year-old patient about 8 weeks pregnant who is

complaining of abdominal pain. Dr Techno cannot identify the cause, and Rosa, a qualified nurse, asks Dr Techno to order a computed tomography (CT) scan, available from the low-dose equipment at the hospital. Dr Techno considers this desirable and safe for Rosa's pregnancy, but is under pressure from the hospital administration to be economic in use of this costly procedure. The local medical association has also urged practitioners to reduce unnecessary resort to CT scans, and the governmental ministry funding the hospital has threatened to limit funding, if running expenses are not contained.

Questions

1. Is Dr Techno ethically obliged to comply with Rosa's request and order a CT scan?
2. Can Dr Techno ethically advise Rosa that the Scan is not strictly necessary for her, and decline to order it?
3. Can Dr Techno consult with a colleague not responsible for Rosa's care, and reach a joint decision on whether or not to order a CT scan?
4. Can Dr Techno exercise clinical judgment to order the CT scan, but invite the hospital administration to veto the decision on grounds of economy?

Assessment

Where reserves on which a population of current and potential patients depends for healthcare are scarce, a physician or other provider is liable to face the dilemma of acting in what is considered an individual patient's best interests, without regard to the effect on other equally dependent patients, or to subordinate that patient's interests to what is considered the general good. The dilemma of double agency arises when an individual healthcare provider is required to serve a particular patient with integrity

and fidelity, but also to serve the interests of a more general population of that provider's and colleagues' other patients in making a rational use of scarce community resources. The microethical expectation of allegiance to the individual patient, sometimes shared by courts of law, requires application of clinical judgment in that patient's interests alone, but a macroethical duty requires care for the wider community of patients.

Ethical Analysis

Respect for Persons

Ethically, Rosa's autonomy would be served by order of the CT scan. The order would also be consistent with not exploiting her vulnerability and dependency that is by not sacrificing her interests to those of other patients. Other patients are vulnerable too, but Dr Techno's decision should be based only on what the doctor considers, in clinical judgment, to be in Rosa's best interests in appropriate diagnosis of her condition, if her autonomy is to have priority.

Benefit and Avoidance of Harm

Dr Techno must assess whether Rosa's beneficial access to diagnosis by CT scan would risk any radiation-related harm to the embryo or fetus she carries, and whether such risk is outweighed by the advantage to her pregnancy of successfully diagnosing the cause of her abdominal pain. A further assessment Dr Techno must make is whether ordering a CT scan for Rosa, though desirable, is so necessary or beneficial as ethically to justify denying the scan to another patient, who may be one for whose care Dr Techno is also responsible. This would present the doctor not with a conflict of self-interest, but with a conflict of commitment. That is—the doctor would have no personal benefit in favoring Rosa over another patient or vice-versa, but might

have ethically to justify withholding an indicated CT scan from one patient while making it available to another. If the benefit of having a CT scan and the harm of being denied a CT scan are ethically equal between the patients, Dr Techno might decide by random chance, such as by flipping a coin, which would give the competing patients an equal chance.

Justice

Dr Techno might complain of the injustice of having to decide to benefit one patient, such as Rosa, at the cost of another. It may also have to be resolved whether it is just to favor a pregnant patient over one who is not pregnant, or to disfavor a pregnant patient when her unrelated chances of not surviving pregnancy are lower, such as in settings with relatively high rates of maternal mortality. Dr Techno might claim an entitlement to use whatever available resources are indicated for Rosa's care, and leave the burden of achieving departmental or hospital economy to an independent manager, such as by making the resources unavailable. That is—Dr Techno may protest against the injustice and breach of ethics of being forced to act as a double agent.

EGG DONATION

Case

Mrs Gage, 42-year-old and childless, is desperate to conceive, after 5 years of trying without success, although her husband has a normal sperm count. Mrs Gage has suffered two miscarriages at 8 and 9 weeks. In consultation with Dr Vita at a fertility clinic, Mrs Gage decides that she requires an ovum donor, but explains that neither she nor her husband have family members or friends who are suitable to donate. Mrs Gage's antral follicle count and anti-Mullerian hormone (AMH) both point to a very low ovarian

reserve, but she has no other medical problems. Ultrasound showed her uterus to be normal and she is in good health with no contraindication to pregnancy. Mrs Gage had emigrated from a country where professional ethics requires ovum donation to be uncompensated and anonymous. She lives in her husband's native country, where donation may be compensated within legally regulated limits, but where professional ethics requires that, on becoming of age, children born of gamete donation be able to learn the donors' names. Dr Vita says that an adult woman recruited from either country can be the donor, but ovum transfer between the countries is illegal. Mrs Gage says that she would like Dr Vita to find a suitable, anonymous donor.

Questions

1. Can Dr Vita ethically bring in a compensated donor from Mrs Gage's native country?
2. Can Dr Vita ethically maintain anonymity of a donor from Mrs Gage's native country?
3. Can Dr Vita ethically advise a potential ovum donor?
4. Should Dr Vita ethically advise Mrs Gage to seek services in her native country?
5. Are there special medical considerations of which Dr Vita should ethically advise Mrs Gage in bringing in a donor from another country, or in Mrs Gage obtaining services in another country?
6. Does Dr Vita have an ethical duty to seek Mr Gage's independent preferences?

Assessment

Female fertility declines with age, especially after 35 and even more rapidly after 40. Premature ovarian failure occurs in 1–2% women, but decreased ovarian reserve is probably more common. The success rate of pregnancy following ovum donation is almost 50%, but

there are slightly increased risks of pregnancy complications including bleeding during delivery and postpartum. The ovum donor will go through in vitro fertilization (IVF) stimulation, which carries a minor risk of ovarian hyperstimulation syndrome (OHSS), and in some countries may be compensated for donation, usually within regulated limits. In some countries, such as France, the donor must be totally anonymous, but elsewhere, such as in the UK, parents must undertake to make donors' names available on request to their offspring when they reach majority age.

Individuals seeking and offering reproductive care services across national borders is a relatively recent phenomenon, the implications of which are being progressively revealed based on experience, anecdotes, and empirical data. The implications of the phenomenon in medical ethics are also under progressive recognition and assessment, disclosed, for instance, in statements, guidelines, and recommendations issued by professional and academic bodies.

Ethical Analysis

Respect for Persons

If Dr Vita endorses Mrs Gage's decision to seek an ovum donor and identifies means of successful recruitment, her desperation to become a parent may diminish her capacity for autonomous choice regarding most appropriate alternative in her circumstances, amongst which are abandoning treatment, and adoption. To promote her autonomy, these alternatives should be explained to her by a disinterested counselor. This raises the ethical issue of whether Dr Vita is disinterested. A further ethical issue is whether Dr Vita has any accountability to Mr Gage in treating Mrs Gage.

For the donor, there is the risk of her autonomous choice of donation being subverted by the inducement of an apparently

high level of payment. If she is in need of money, she may be vulnerable, and in need of independent advice on the risks of undergoing donation, such as of OHSS. Dr Vita's primary duties are to Mrs Gage, raising the ethical concern of whether the doctor can at the same time treat and advise the prospective donor as a patient.

Benefit and Avoidance of Harm

For many women with access to reliable maternal healthcare, the benefit of becoming a parent far outweighs the risks inherent in any pregnancy, although the risk is slightly higher than normal for Mrs Gage, if she receives one or more donated ova. An ethical issue is whether Dr Vita needs to take account of whether Mr Gage would see his wife's pregnancy and motherhood as a benefit.

A potential ovum donor would have to assess the benefit to her of paid or altruistic donation against the risks of suffering harm, minimal as they usually are (OHSS, bleeding, and infection at ovum retrieval). Disinterested, informed counseling is essential for the donor's understanding of all potential implications of her donation, both beneficial and harmful, including knowing that another woman may be rearing her biological child, and that in years to come that child may contact her. The risks of repeated donation are unknown at present.

Justice

In most countries where donation is practiced, there is a severe scarcity of donated ova compared to the demand. An ethical issue is whether donated ova can justly be allocated to former cancer sufferers or, for instance, Turner syndrome sufferers, in priority to older women who might have conceived with their own ova if younger. This may place the ethics of maximum use of scarce medical resources and the human right of nondiscrimination

on grounds of disability in competition with each other. Furthermore, many women travel to other countries for ovum donation because at home it is legally forbidden or there are lengthy waiting lists. This may deprive citizens of the countries to which they go of medical care, especially if they are resource-poor countries that do not offer citizens all basic healthcare. This may aggravate international healthcare inequalities, while at the same time bringing valuable income to poor countries that may be fairly distributed within the health sector.

FEMALE GENITAL CUTTING/ MUTILATION

Case

Kani, aged 20, married for 2 years, reported to Dr Magum that she had been unable to conceive. She had marital problems and was about to be divorced because of her inability to become pregnant.

On examining her, Dr Magum found that the marriage had not been consummated due to infibulation, the most severe form of female genital mutilation (FGM), performed on her by a midwife when Kani was aged 7. She also had a swelling resulting from this traditional practice, which was causing her a great deal of inconvenience.

Questions

1. What should Dr Magum ethically propose for Kani's benefit?
2. Does Dr Magum have an ethical duty to explain to Kani's husband why the marriage has not been consummated?
3. Does Dr Magum have an ethical duty to seek and report the identity of the midwife who performed the procedure?
4. Does Dr Magum have an ethical duty to the family and/or community from which

Kani came to give instruction on the harms of FGM?

Assessment

The case of Kani illustrates the health risks that can be inflicted by the harmful traditional practice of female genital cutting, often described as mutilation (FGM). This practice, which is not based in any religion, is prevalent in a number of countries, mainly in sub-Saharan Africa. It is now also seen in Europe, North America, and other countries among populations that have migrated from affected regions. Many young girls are subjected to the practice, which is a violation of the rights of the child. If performed by medical or other health professionals, the practice is usually taken to constitute professional misconduct.

The consequences to Kani were a tumor (dermoid cyst) and tight infibulation, which is preventing the consummation of her marriage, resulting in infertility. The emotional and marital damage to Kani is great and could cause her to be divorced. She may also suffer additional burdens of ill health due to complications of infibulations.

Ethical Analysis

Respect for Persons

When undertaken on young children incapable of exercising choice, female genital cutting exploits their vulnerability and constitutes violation of their rights, such as to health. It is ethically questionable whether younger adolescents who accept the procedure as a rite of passage into adulthood in their communities are really exercising their autonomy when they are subjected to family and community pressures they lack means to resist. However, the wishes of adult women capable of autonomy who have conceived and given birth after being unstitched, and

who then request reinfibulation, may be respected, although this is professionally condemned on health grounds and as risking condoning an earlier wrong.

Although used, for instance, by WHO, the description “mutilation” is ethically problematic. Infibulation, as the most severe genital procedure, may warrant this description, but lesser forms of token genital cutting may be unjustly condemned by this word. Among communities that have traditionally undertaken this practice, it is often explained as a form of purification. Female genital cutting risks and often causes multiple harms, so belief in its appropriateness appears misguided. However, the belief may not justify a description designed to draw disrespect and condemnation upon caring parents who have been conditioned by their culture to accept it.

Benefit and Avoidance of Harm

It would appear beneficial to Kani if Dr Magum, by appropriate means, rendered her capable of sexual intercourse with her husband, with a view to creating a family. Beyond this, Dr Magum would promote the couple's greater benefit by explaining to them, preferably together but separately, if their culture disallows discussion of sexual matters in mixed company, the means of sexually expressing intimacy and love. Kani's husband may know about sex from older men, perhaps in crude terms, and before marriage Kani's mother or close female family members may have told her, perhaps in euphemistic terms, about a wife's expected submission to her husband. A disadvantage of such information is that it may incorporate inaccuracies, folklore, myths, and dysfunctional stereotypes. It is preferable that Dr Magum should provide the information that, with treatment and understanding, they may not be an infertile couple, but may realistically look forward to having a family together.

For avoidance of future harm, Dr Magum may also inform them of the physical and emotional harm to which female genital cutting often leads and that it should not be conducted on a daughter or other female family member of theirs. To maximize the benefit of this education, Dr Magum should consider providing information to them individually, jointly, and/or communally.

Justice

If local law requires reporting of known instances and perpetrators of female genital cutting, Dr Magum may be required reasonably to seek the identity of the person acting on Kani, and to inform appropriate law enforcement and/or professional licensing authorities. If no such duty exists, the doctor may have discretion in good faith to report misconduct to professional authorities, and child abuse to law enforcement authorities, although this may place Kani's parents at risk.

At the level of social justice, Dr Magum should consider initiating or contributing to community education on the harm and wrong of female genital cutting, and urge its eradication from the community and culture in order to spare future children from suffering this unnecessary injury. The doctor may try to enlist the aid of religious and other community leaders in this endeavor.

HEPATITIS B VACCINATION

Case

Dr Adams, a clinician and influential consultant to the government medical insurance plan in a developing country with low resources, conducts routine antenatal screening on Eve, a 30-year-old HIV-positive pregnant patient with a CD4 count of 950 and undetectable viral load [on antiretroviral (ARV) therapy].

Dr Adams found Eve to be hepatitis B surface antigen positive (HBs +ve) and hepatitis e antigen positive (HBe +ve) with no antibodies to both surface and e antigens. Her liver function tests are completely normal. She is classified as a chronic carrier of hepatitis B. What are Dr Adams ethical choices in advising Eve and in making recommendations to the government medical insurance plan?

Questions

1. Should Dr Adams ethically recommend that the pregnancy continue, when local law would allow its termination?
2. Should Dr Adams ethically recommend that Eve deliver by cesarean section, and that all other pregnant patients chronically infected with hepatitis B deliver in the same way?
3. In Dr Adams' developing country where HIV is highly prevalent, should all HIV-positive individuals be tested for hepatitis B, and vaccinated when they test positive?
4. Should Dr Adams recommend that vaccination for hepatitis B be a prescribed minimum benefit under the government medical insurance plan?

Assessment

The hepatitis B virus is one of the most common human pathogens worldwide. Up to 95% of HIV-infected individuals have been infected with hepatitis B. Sexual transmission is the most common route of transmission. In pregnancy, most transmission of hepatitis B virus infection occurs around the time of delivery through contact with contaminated vaginal secretions or blood. HIV/hepatitis B coinfection increases liver mortality 15 times more in than in an HIV-negative individual. Progression to hepatocellular carcinoma is

increased by five times especially in patients with chronic hepatitis B. All patients infected with HIV but negative for hepatitis B should be vaccinated. Approximately, 30% of HIV-infected patients have a nonresponse. The response to the vaccine is influenced by the CD4 count and the level of HIV. Patients with CD4 less than 200 and who are not on therapy should receive ARVs first and then be vaccinated when there is a good response to ARVs.

Ethical Analysis

Respect for Persons

Dr Adams may advise Eve who is HIV-positive to continue with her pregnancy since her liver function was normal, but it would be entirely up to her to decide whether she should opt for the termination of pregnancy or carry her baby to term, bearing in mind that being HIV-positive and an hepatitis B carrier can transmit the virus to her newborn during pregnancy or delivery.

While autonomy entails respecting the rights of other individuals to freely determine their own choices and decisions, Eve and other patients with the same condition are vulnerable to liver disease and respect for persons necessitates Dr Adams to arrange that such patients be also seen by a liver specialist.

Benefit and Avoidance of Harm

On the basis of the principle of *beneficence*, it may be plausible to have all patients infected with HIV but negative for hepatitis B vaccinated. However, it is to be noted that approximately 30% of HIV-infected patients have a nonresponse in view of the fact that response to the vaccine is influenced by the CD4 count and the level of HIV. Patients with CD4 less

than 200 and who are not on therapy should therefore receive ARVs first and then be vaccinated when there is a good response to ARVs.

Moreover, it is to be noted that in pregnancy most transmission of hepatitis B virus infection occurs around the time of delivery through contact with contaminated vaginal secretions or blood. It may be sound on the part Dr Adams to recommend that Eve deliver by cesarean section, and that all other pregnant patients chronically infected with hepatitis B deliver in the same way. Furthermore, in order to avoid harm, Eve's newborn child must be given two shots in the delivery room—(1) the first dose of hepatitis B vaccine and (2) one dose of hepatitis B immunoglobulin (HBIG). If these two medications are given correctly within the first 12 hours of life, a newborn has a 95% chance of being protected against a lifelong hepatitis B infection. The infant will need additional doses of hepatitis B vaccine at 1 and 6 months of age to provide complete protection.

Justice

On the societal level, while taking into account that hepatitis B is not transmitted casually and that it cannot be spread through sneezing, coughing, hugging, or eating food prepared by someone who is infected with hepatitis B, it would be justified to make members of a household aware that there is an infected family member living in their household and that they should be vaccinated.

Dr Adams should definitely recommend that vaccination for hepatitis B be a prescribed minimum benefit under the government medical insurance plan for that would be cost-effective in the long run and would also circumvent vulnerable females from contracting liver cancer.

HUMAN PAPILLOMAVIRUS VACCINATION

Case

Dr Physio is medical officer for a school for children of both sexes aged 5–15. There is a high rate of cervical cancer in the region, which has orphaned several of the children. The local government has introduced a preventive program of human papillomavirus (HPV) vaccination for schoolgirls aged from 9 years upwards. The school principal asks Dr Physio, how pupils at the school can receive maximum protection?

Questions

1. What should Dr Physio advise?
2. What should parents be told?
3. What should schoolgirls be told?
4. What account should be taken of schoolgirls' wishes?
5. Can vaccination of schoolgirls be compulsory?
6. Should schoolboys be treated in the same way as schoolgirls?

Assessment

In 2006, a vaccine against the oncogenic types 16 and 18 of HPV was licensed. A number of countries have recommended vaccination of girls between the ages of 11–17 with catch-up vaccination up to age 26. There is limited data on the safety and efficacy of the vaccine in some circumstances, and on failure to have follow-up vaccination. Most sexually active people will contract HPV at some time in their lives, usually with no awareness or effects, but it can dispose women to eventual cervical cancer, and premature death. Protection by HPV vaccination is most effective when it is undertaken before girls' first sexual intercourse. The interaction between HIV and HPV is complex. Warts are more common in

HIV-positive than in HIV-negative patients. There is evidence that HPV infection in HIV-positive patients progresses to dysplasia and cervical cancer.

Ethical Analysis

Respect for Persons

Dr Physio may advise the school principal to consider implementing HPV vaccination for girls at the school above a given age, such as 11 years, to inform girls' parents and guardians of the school's intended program of vaccination, and to request their consent. The autonomy of parents or guardians (hereafter "parents") over the children for whose well-being they are responsible is not absolute, because parents are bound by ethical and often legal duties to protect vulnerable children, and to make decisions concerning them, including regarding their health and welfare, in their best interests.

The capacity of children to make choices regarding their healthcare will frequently be influenced by the cultural background of the families concerned. Laws often set ages beneath which legal minors lack capacity, for instance to purchase tobacco products or drive motor vehicles, but many accept that "mature minors" may make therapeutic and preventive healthcare decisions for themselves. They may decline treatment their parents approve, and in particular give effective consent to beneficial or protective medical treatment without parental consent. It is an ethical decision whether mature minors should be offered protective medical procedures without parental approval, and whether mature minors' confidentiality should be respected, so that they choose whether their parents are informed.

Benefit and Avoidance of Harm

Parents may be slow to acknowledge that their young daughters, like all members of the

human species, are sexual beings, and that they may become sexually active before parents believe they will. Parents should be told that consenting to vaccination of their daughters is in the best interest of their children's protection, that vaccination is proposed for them before they decide to become sexually active, and that it could well serve as a protection for them in the event of sexual assault. Schoolgirls should be made aware that the HPV vaccine is a preventive measure against cervical cancer.

Parents and others may believe that administering such a vaccine to prevent adolescent girls from contracting a sexually transmitted virus could promote their sexual promiscuity, and hence the principle of *nonmaleficence* would justify nonadministration of HPV vaccination. However, it may be unlikely that teenage girls would give the risk of their contracting HPV the same weight as they give to the risk of pregnancy in their choices to engage in sexual activity. The actual benefit of HPV vaccination for adolescent girls would far outweigh the potential harm of vaccination contributing to their sexual precociousness. In light of this, such vaccination may be made compulsory by the state, if it is of the view that relying exclusively upon parental autonomy could be harmful to the children's health and welfare. For example, parents may suggest that such vaccination should be given only to daughters who are above compulsory school age, for instance, 15- or 16-year-old. Therefore, to promote preventive care for minors, the state may require vaccination of preadolescent girls while they are conveniently gathered in schools. The vaccine is effective only if administered prior to girls' exposure to the virus and will not treat existing infections, but may serve to reduce the eventual harm, to women and others, such as their children, of women succumbing to cervical cancer.

Hence, the state and schools may justify compulsory HPV vaccination of preadolescent girls before they indulge in any form of sexual activity, including sexual contact without intercourse.

Justice

Since the principle of *justice* entails treating both girls and boys alike, it logically follows that preadolescent boys as well as girls should be vaccinated for HPV, particularly since females contract the infection from males. However, a new and an accompanying editorial published online (October 8, 2009) in the *British Medical Journal* suggests that vaccinating boys against HPV in addition to girls is not likely to be cost-effective. This raises the issue of whether there is an ethically relevant difference between the sexes in this regard.

HYSTERECTOMY

Case

Luz is 41-year-old and works in customer service at a department store. She is unmarried, but for many years has enjoyed an active sexual relationship with her 43-year-old man friend. Her mother died of cervical cancer 20 years ago, as did her older sister 3 years ago.

Luz has suffered uterine bleeding for the last 3 years due to multiple uterine leiomyomas and is slightly anemic. She does not want children. She came to visit a gynecologist, Dr Perez, who had cared for her older sister, knowing from her own reading and research that hysterectomy is the best treatment alternative for her pathology. However, she does not want her uterine cervix removed, and wants no changes in her sexuality or capacity for sexual enjoyment. Doctor Perez said that she needs a total abdominal hysterectomy and argued that since cervical cancer is the most frequent women's cancer in the country,

her uterine cervix should not be retained for any reason. Doctor Perez works for the governmental Social Security medical service, but Luz belongs to a private health insurance plan. Under its terms, she went to a private gynecologist, Dr Salas, who explained that a subtotal hysterectomy is an alternative treatment, since Luz has had normal Pap smears throughout her reproductive life. Dr Salas emphasized her need to continue to have annual Pap smears.

Questions

1. Should Dr Perez have asked Luz about her sexuality before addressing the treatment options and making a recommendation?
2. Should the patient's preferences and reasons and the reasoning of Dr Perez have been balanced against each other before a decision on a surgical technique was made?
3. Should Dr Salas have taken account of the patient's liability to suffer cervical cancer?
4. What is the ethical significance of Luz's family history of cervical cancer deaths?

Assessment

In the 1950s, improvements in surgical technique and the desire to prevent cervical cancer resulted in the adoption of routine removal of the cervix with the rest of the uterus at the time of hysterectomy. Currently, there is a resurgence of interest in leaving the cervix in place at the time of hysterectomy.

In 1983, Kilkku published a study showing more frequent orgasms after supracervical hysterectomy than after total hysterectomy. It was argued that the nerves in the cervix are important for orgasm. This was a retrospective study in which there was no baseline assessment of the subjects, so it is impossible to draw any meaningful conclusion.

Although we have very good screening methods for cervical cancer, and adenocarcinoma is increasing in frequency. There is a small but definite risk of cancer in a remaining cervix.

Masters and Johnson's pioneering studies of the female sexual response suggested that, at least in some women, the uterus plays a role in the physiology of vaginal orgasm, so the supracervical hysterectomy, by preserving nerves and ligaments, helps to preserve normal postoperative sexual function. Some authors in reviewing the arguments remain unconvinced of these purported advantages.

Recently, in 2010, Dr Ellström published a randomized clinical trial, comparing changes in sexual health between women with subtotal and total hysterectomies, and concluded that "women undergoing subtotal hysterectomy experience a greater positive change in the frequency of orgasm and extent sexual pleasure after surgery than women undergoing total hysterectomy".

Ethical Analysis

Respect for Persons

The first doctor Luz visited took relatively slight account of the principle of autonomy, giving greater attention to saving her from the risk of cervical cancer. However, Luz was reading and obtaining information about her pathology and the treatment options. Dr Perez made a recommendation based on what healthcare intervention will be the best for her, considering biological reasons, rather than based on her enjoyment of her sexuality or on the psychological implications of treatment for her.

Benefit and Avoidance of Harm

The gynecologist Dr Perez thought to benefit and protect the patient's physical health, but performing a total abdominal hysterectomy

may harm the patient's sexual and psychological health, and affect the quality of her relationship with her man friend.

Justice

Luz could be offered a subtotal hysterectomy because she has means to be a member of a private health insurance plan. Other similarly situated women who have only dependency on the Social Security medical service plan might not have the option of the surgical procedure that they reasonably want. They might be confined only to care such as Dr Perez offered. Under the principle of justice, the quality of life and the well-being of each person should be taken equally into account.

ILLITERATE PATIENTS' INFORMED CONSENT

Case

Anna, aged 24, resident in a resource-poor rural area, is about 20 weeks into her second pregnancy. Her first child, aged 3, was delivered vaginally after a complicated pregnancy. Her present pregnancy is also proving difficult, and her doctor, Dr Nomina, is considering whether an episiotomy or a cesarean delivery may be necessary, and if so, which Anna would prefer. Anna and her husband are unable to read, fearful of Anna being cut, and intend to have several subsequent children. Dr Nomina has shown them illustrations of the two procedures, and is concerned whether Anna and her husband adequately understand the implications of their choices. The doctor does not want them aggrieved after the second child's birth that they were not informed about how delivery might be managed, the effect on their resumption of love making, and on subsequent deliveries.

Questions

1. Can Anna and her husband exercise choice of preference?
2. How can Dr Nomina maximize the understanding Anna and her husband have of options that may arise?
3. How can Dr Nomina ethically minimize grievance that Anna's options were not adequately explained?
4. Can Dr Nomina ethically compromise best care of Anna in order to accommodate her preference?

Assessment

Both episiotomy and cesarean delivery may leave scar tissue, cause discomfort, risk infection, and may affect subsequent deliveries. Though better avoided if possible, a choice of one option or the other may prove necessary to facilitate safe delivery and reduce delivery-related injuries to newborns. Aftercare of mothers may require skilled attention, such as by midwives. Counseling in anticipation may be aided by patients consulting with women who have experienced these procedures and, subject to preservation of confidentiality, patients' comprehension and expression of preferences may be witnessed by independent third parties before notation of their choices in patients' medical records.

Ethical Analysis

Respect for Persons

Patients' illiteracy does not deny them the right of choice or capacity for making competent decisions. However, their dependence on oral communication limits their access to more information than they can be told and can remember, which leaves them vulnerable to bias in presentation and distortions of memory, and their inability to maintain their decisions in writing leaves them vulnerable

to others' recording of what they decide. Disinterested witnesses might reliably show that patients received information, had opportunities to ask questions, and made particular decisions or choices, but at the cost of patients' rights to confidentiality.

Benefit and Avoidance of Harm

It is of benefit to patients that they be facilitated, by means they comprehend, to assess their options and make their decisions, although patients' power of self determination may result in them making adequately informed but unwise, potentially harmful decisions. Healthcare providers' initiatives to protect patients against their poor choices by actions, patients do not comprehend and to which they therefore do not give their informed consent, may be well intended, but are paternalistic and offensive to patients' dignity as decision makers over their own bodies and health.

Justice

The integrity of Dr Nomina's disclosures to Anna, and of Anna's unimpaired exercise of choice, may be confirmed by a disinterested third-party witness, but the primary purpose of the witness is to protect Dr Nomina against a subsequent charge of acting without consent or contrary to Anna's wishes. That is—Anna may be encouraged to forgo her right to confidentiality by introduction of a third party witness—in order to protect not her but the doctor's interests. Dr Nomina is entitled to protection against allegations of misconduct, but it is of ethical concern when doctors and similar actors who enjoy the power of knowledge and influence encourage less powerful patients who depend on them for care to forgo their rights, such as to confidentiality, for protection of the more powerful actor's interests.

INVOLUNTARY FEMALE STERILIZATION

Case

Mrs Magoe, aged 34, has four children and is pregnant again. She and her husband are very poor and decide to begin to use efficient government-funded contraception after delivery. She attends a government-run hospital to see Dr Deen, seeking advice on an appropriate contraceptive method. There is a concern in the country about the increasing population growth, and all hospitals are under pressure from the government to increase contraceptive use and to decrease fertility. The government has recently adopted a national regulation stating that any woman with three or more children can continue to have free hospital delivery only if she agrees to be sterilized after delivery. Furthermore, disciplinary action will be taken against any noncompliant hospital physician who provides delivery without charge for a fourth or subsequent child.

Questions

1. Would it be ethical for Dr Deen to pressure Mrs Magoe to agree to sterilization, even though she is reluctant?
2. Is Dr Deen ethically bound to deny Mrs Magoe unpaid hospital delivery unless she accepts sterilization, knowing that she cannot afford to pay for hospital services and that medically unattended delivery of her fifth child would be hazardous?
3. Would it be ethical for Dr Deen to deny Mrs Magoe contraceptive care, saying that sterilization is her only choice?
4. Would it be ethical for Dr Deen to supply a long-acting contraceptive means, and certify that Mrs Magoe has been sterilized (by a method with the highest failure rate)?
5. Would a vasectomy for Mr Magoe, with the possibility of reversal, ethically satisfy Dr

Deen's obligation to reduce the chance of Mrs Magoe having another child?

Assessment

Female sterilization is a safe, simple, and very effective surgical procedure. It can usually be done under local anesthesia and light sedation. Postpartum sterilization is done by minilaparotomy (a small abdominal incision).

Because female sterilization should be considered permanent, the decision made by the woman must be based on voluntary informed choice and should not be made under stress or pressure. Other methods of contraception should be introduced and offered, to allow women to make free choices. The intrauterine device is a good alternative for women who want long-term contraception, and long-acting subcutaneously implanted contraceptive rods are also available.

Ethical Analysis

Respect for Persons

The aim of family planning programs is to enable couples and individuals autonomously and responsibly to decide the number and spacing of their children, to have the information and means to do so, and to ensure informed choices. This aim includes making available a full range of safe and effective methods, including female and male sterilization. The FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health, in outlining ethical considerations in sterilization, stated in 2000 that "No incentives should be given or coercion applied to promote or discourage any particular decision regarding sterilization. In particular, withholding other medical care by linking it to sterilization is unacceptable".

The principle of respect for persons includes due protection of vulnerable individuals.

Mrs Magoë is vulnerable to involuntary sterilization or the hazards of delivering her fifth child without medical care, due to her poverty. Dr Deen is not accountable for this, but the government policy exploits her financial inability to pay hospital costs of childbirth to induce her to accept sterilization against her choice. Dr Deen may ask the disciplinary authorities for permission to provide Mrs Magoë with safe, unpaid delivery of this child, and appropriate contraception. The FIGO 2000 statement concludes that "At a public policy level, the medical profession has a duty to be a voice of reason and compassion, pointing out when legislative and regulatory measures interfere with appropriate medical care".

Benefit and Avoidance of Harm

It is legitimate for a government to be concerned about rapid population growth and its harmful impact in impairing socioeconomic development. Promoting awareness and provision of family planning services, including education and information on voluntary sterilization for men and women, is beneficial social measure. Furthermore, a woman's repeated pregnancy, especially at short-birth intervals, presents increasing risk for the mother and her future children's health. However, a government policy that operates to deny poor women necessary medical care in childbirth is harmful to both mothers and their children. It is also injurious to the dignity of poor families that, unlike families of greater means, their medical providers are required to offer them desirable health services only on condition of their acceptance of an oppressive option.

Justice

When there are limited state resources, and free delivery of maternity care is linked to

acceptance of another measure like sterilization, the policy may unjustly deny care to women of relatively high parity, compelling them to forgo care or seek services, including abortion, from unqualified providers. All pregnant women should receive similarly safe care in pregnancy. The policy is unjust in addition for its discriminatory focus on sterilization of women having children, and not addressing male procedures.

Dr Deen should be able to provide Mr and Mrs Magoë, equally with other patients, with enough information of contraceptive methods appropriate to their needs, including sterilization and reversible forms of family planning, which are comparably effective. Mr and Mrs Magoë should be properly counseled concerning the risks and benefits of sterilization and of its alternatives, and exercise choice unrestrained by their limited funds. Human rights principles protect individuals against medical procedures to which they do not freely consent, and the concept of reproductive health includes "the capability to reproduce and the freedom to decide if, when and how often to do so". Dr Deen can invoke the physician's ethical duty of equal respect for all patients in order not to require pregnant women unable to pay for indicated hospital delivery services to agree in advance to sterilization as a condition of receiving free care, and speak out against the injustice of a policy that compromises the voluntary treatment of poor women.

MULTIPLE PREGNANCY

Case

Reba, aged 40, has been childless throughout her 16 years of marriage. She and her husband inform Dr Paulin, who is a specialist at an infertility clinic, that they want to have a baby before Reba is 42. They request hormonal stimulation of ovulation either to enhance

natural reproduction or for IVF, perhaps with intracytoplasmic sperm injection (ICSI), in either case to maximize the chance of a singleton pregnancy. Dr Paulin is aware that hormonal stimulation of ovulation and multiple embryo transfer in IVF may result in multiple pregnancy, although transfer to her uterus of more than a single embryo may be indicated for Reba due to her advanced maternal age.

Questions

1. Can Dr Paulin ethically recommend hormonal stimulation for natural fertilization knowing that dosage levels can achieve effects from failure of fertilization up to high multiple pregnancy?
2. Can Dr Paulin ethically advise hormonal stimulation for IVF, intending that any surplus embryos, which are likely to remain, would be used for transfer to others, research or teaching, provided that Reba consents?
3. Can Dr Paulin ethically require fetal reduction, if Reba has a triplet or higher multiple pregnancy?
4. Can Dr Paulin ethically comply with Reba's request to reduce a twin to a singleton pregnancy?

Assessment

Hormonal stimulation for natural reproduction risks unpredictable levels of multiple pregnancy, whereas in IVF, doctors can control the number of embryos transferred. For women aged 35 and over, transfer of more than a single embryo is often advised, to increase the chance of pregnancy and childbirth. However, up to the age of 40, it has been shown that repeated single embryo transfer (SET), after freeze/thawing if necessary, is as efficient as multiple embryo transfer. In the UK, just under a quarter of live births from IVF are of twins, down from

nearly a third in 2008, reflecting a policy favoring SET. Women seeking medically assisted reproduction (MAR) tend to be of relatively advanced age, however, which is often considered to justify stronger means to stimulate ovulation, and uterine transfer of more than single embryos, both of which increase the possibility of multiple pregnancy.

Ethical Analysis

Respect of Persons

Hormonal stimulation of Reba increases her prospects of achieving a desired pregnancy, whether by natural fertilization or IVF. She is vulnerable, however, to a clinic's proposal to treat her only on the condition that she accepts to continue a twin pregnancy, since, in the event of multiple pregnancy, the clinic will not undertake fetal reduction to singleton birth as a matter of principle and economical use of limited resources. There are ethical concerns, however, about requiring or conditioning a woman to have more children than she really wants. This would compromise her autonomy, and leave the risk of jeopardizing her health and that of the fetuses in utero and the children-following birth.

Benefit and Avoidance of Harm

Facilitating a patient to overcome infertility and have the child she wants is beneficial, but the risk of multiple pregnancy, even of no more than twins, is increasingly regarded as a complication or dysfunction of many forms of MAR. Hormonal stimulation itself creates a risk of OHSS, which has proven fatal, although in modern times, this risk is usually well controlled. The main burden of multiple pregnancy is to fetuses in utero, children at (often premature) birth, and prenatally and postpartum to the women who bear them. It was observed in the UK in 2007 that the still-birth rate for multiple pregnancies was four

times higher than for singletons, and that multiple gestations are a substantial contributor to overall perinatal mortality rates. Beyond individual costs are the social costs to hospital and healthcare systems of coping with the neurodevelopmental impairments and respiratory and gastrointestinal complications to which pre-term babies are particularly prone.

Justice

The effect of a patient accepting the risks to herself and her twin or more newborn children of multiple birth may be to burden a public healthcare and educational system with the costs of prolonged responsibility for their well-being. This raises ethical questions of social justice, and has inspired some healthcare systems in developed countries to subsidize MAR in order to promote SET, and perhaps multifetal reduction. Some may see reduction as abortion of the implanted embryos or fetuses sacrificed in utero, but the FIGO guidelines observe that reduction of greater than a twin pregnancy “is not medically considered as terminating that pregnancy but rather as a procedure to secure its best outcome”. If ultrasound or other means show a fetus in utero to be severely impaired, its selective termination raises ethical issues of implied devaluation of handicapped members of the community. If all fetuses are of equal potential, the selection of one or more for termination raises ethical concerns of achieving equality in random targeting.

OBSTETRIC FISTULA

Case

Shala, aged 16, married for the last 2 years, lives in a remote underserved area.

She had her first pregnancy at the age of 15, and no antenatal care was available to her. Labor was under the care of a traditional birth attendant (TBA), with no facilities or support

for emergency obstetric care. After 3 days in prolonged and obstructed labor, she delivered a stillborn baby, and observed urine leaking 3 days later. The TBA could give no advice on that, and the nearest hospital capable of providing treatment and support is 300 kilometers away, with no facilities for easy transportation. Shala's family and her husband's are too poor to afford travel expenses. She became depressed, and her husband left her, as well as her friends. She is required to live in isolation outside her village, and not to join in preparation of food for others.

Twelve months ago, a small health clinic was established 5 kilometers from the village, staffed by two nurses and a midwife. Dr Perri, a gynecologist at the distant hospital, spends 10 days at the clinic every 4 months. Shala's father took her to the clinic, where Dr Perri examined her, and found that she has a vesicovaginal fistula (VVF) and a rectovaginal fistula (RVF).

Questions

1. Is Dr Perri ethically bound to assist Shala to cope with her condition?
2. Should Dr Perri ethically pressure the hospital to offer fistula repair services for Shala?
3. Should Dr Perri seek to equip the clinic to undertake fistula repair?
4. Does Dr Perri have wider ethical responsibilities to potential patients in Shala's circumstances?

Assessment

The case of Shala illustrates a number of issues related to injustices in the provision of essential healthcare, including concerns related to early marriage, and the lack of sensitivity in the medical care system to the provision of care needed by impoverished individuals, families, and communities.

Early marriage is a harmful traditional practice prevalent in developing countries, and Shala is a victim of this social injustice, exposing her to early pregnancy and premature childbirth, which is liable to result in maternal death or, among other disorders, affliction by the major disability of VVF/RVF.

Shala's tragedy is being faced by thousands of young women in developing countries, and highlights the social injustice that has to be addressed by communities and their governments. Medical care in general and reproductive health care in particular raise concerns that governments need to address as a priority. Access to essential health services is a basic human right and should be central to the mission of governments committed to the welfare of the populations they claim to serve.

Ethical Analysis

Respect for Persons

Shala's autonomy would clearly be served by Dr Perri affording her the means to access fistula repair, but an earlier issue of her autonomy concerns her marriage. In some traditional cultures, girls are married at an early age, to relieve parents of providing for them, or to relieve their fear that their unmarried adolescent daughters will become sexually curious, then active, and then pregnant, or that unscrupulous men will sexually abuse them, in either case resulting in family dishonor. Dr Perri alone can probably do little to affect this directly, but can give voice and support to laws that protect adolescents' human rights to independence appropriate to their maturity, including enforcement of minimum age of marriage laws, and to everyone's human right to marry only voluntarily.

More immediately, recognizing that fistula repair may not be feasible in Shala's

current circumstances, Dr Perri has to address her incontinence of urine and vaginal feces and associated liability to infection. This may require mobilization of the clinic's resources and gathering family and community resources to maintain her hygiene and morale.

Benefit and Avoidance of Harm

Dr Perri travels between the hospital, 300 km away, and the local clinic every 4 months. The doctor should therefore enquire whether Shala and perhaps a family member could be company on a journey to reach the hospital's fistula repair service. In addition, Dr Perri should see whether the local clinic's midwife or nurse might be trained to undertake diagnosis, management, and repair of at least the more simple fistulas.

Dr Perri's ethical duties of promoting benefits of members of the community dependent on the local clinic and minimizing harm they are liable to suffer includes informing and educating them about the hazards of adolescent girls' early marriage and premature motherhood, perhaps illustrated by the case of Shala, with which they will be familiar. Instruction should address not only health hazards, but also the devastating effects on families, both of a married couple and of each partner.

Justice

The transcending injustice leading to the tragedy affecting Shala and innumerable other young women who are, or are at risk of becoming, similarly situated, is their lack of prenatal care and skilled attendance at birth, including means of timely referral in case of emergency such as unduly prolonged labor. Many governments explain their failures to allocate resources to health services by poverty, but many national governments

conceive of defense of their populations primarily in military terms, such as in the manufacture or purchase of weapons and other armaments. If they could be inspired or required to divide budgets, so that expenditure per capita of population on health defense equaled that on military defense, health protection of their populations might be considerably improved. As a healthcare professional in gynecology, Dr Perri might be ethically expected to urge with colleagues and actively promote adequate funding of prenatal and childbirth services to allow the Shalas in the communities the doctors serve safely to deliver and raise healthy children.

REFUSAL OF CESAREAN SECTION

Case

Regina, aged 28, a married woman living with her husband and 4-year-old daughter in modest circumstances, is in hospital experiencing uterine contractions near the end of her uneventful second pregnancy. Dr Obstet, interpreting readings of the fetal heart rate monitor, fears that her fetus, which has been shown to be male, may lack adequate oxygen supply, and advises Regina to have a cesarean-section delivery. Regina declines—saying she wants natural delivery. Dr Obstet describes the risk of fetal brain damage, but Regina says she will not consent to surgical delivery, unless her or the fetus's life is in danger. When Regina's husband asks about her progress, Dr Obstet explains the position. The husband says he will approve cesarean-section delivery, paying the extra cost with all of the family's savings, so that his son is not brain damaged.

Questions

1. Is Dr Obstet ethically bound by Regina's refusal?
2. Can Dr Obstet ethically act on the husband's approval?
3. Can Dr Obstet ethically risk the family's savings on surgery that may not prevent fetal brain damage?
4. Can the husband claim to speak on behalf of the fetus?

Assessment

Dr George Macones, who headed development of the American College of Obstetricians and Gynecologists (ACOG) July 2009 Practice Bulletin on Electronic Fetal Monitoring (EFM), has noted that EFM has not reduced rates of perinatal mortality or cerebral palsy, although use has reduced risk of neonatal seizures. During labor, EFM has little effect in reducing rates of cerebral palsy, because 70% of cases occur before labor begins and only 4% are attributed solely to events during labor and delivery.

When EFM indicates risk to the fetus, interventions are possible, such as increasing the woman's oxygen supply and/or inducing vaginal delivery possibly with use of forceps, without resort to cesarean-section delivery. An effect of availability of EFM is a significant increase in cesarean deliveries. The ACOG Practice Bulletin was published in July 2009 to reduce the rate of cesarean-section deliveries that are unnecessary. Cesarean-section delivery is usually safe, but this surgical procedure is far more costly than natural delivery, and does present some risks to the mother and/or baby. It may also raise complications in the woman's subsequent pregnancy.

Ethical Analysis

Respect for Persons

Respect for Regina's self-determination or autonomy should make her refusal conclusive,

but she will accept surgical delivery, if there is danger to life. Dr Obstet's duty of truth-telling precludes claiming that Regina's life is at risk. Risk to the life of the fetus/child is a matter of medical assessment, to be made in good faith and not instrumentally in order to justify cesarean-section delivery. The fetus may be vulnerable and so merit protection, but Regina is vulnerable to being pressured or manipulated into cesarean-section delivery that she disfavors, to the risks to her and her fetus of surgical delivery, and to Dr Obstet's superior knowledge. This justifies her protection against subjection to unwanted surgery, which may be futile, if the fetus is already damaged, and unnecessary.

The husband's preferences warrant respect, but he cannot legally authorize surgery his wife refuses, unless perhaps her life is at immediate risk. Similarly, he is not necessarily more ethically entitled to claim to represent the interest of the fetus than is Regina, although prevention of avoidable severe injury to the fetus and child on birth is an important value.

Benefit and Avoidance of Harm

Cesarean-section delivery may benefit the child on its birth, but also poses risks to the fetus, and to the mother in this case or in her later pregnancy. The rule that any later pregnancy will require cesarean-section delivery is no longer as firm as it once was, but account must be taken of this in Regina's circumstances, in assessing the benefit-to-risk ratio. Cesarean-section delivery in experienced hands is usually considered a safe procedure, but may financially burden a family that must meet costs from its own resources, or deplete healthcare resources on which other patients depend.

Justice

Dr Obstet should consider whether a motivation to favor cesarean-section delivery would protect the doctor's reputation for care at the cost of burdening Regina and/or her fetus with the risks, and her family with the expenses, of perhaps futile or unnecessary surgery. That is—Dr Obstet will have to resolve any ethical conflict of interest. The family has limited means, which may be applied for the daughter's benefit, if they are not exhausted by the costs of a cesarean-section delivery of a son. The risk of family impoverishment and deprivation may be a natural burden of membership of a family in which meeting the needs of one may be at the cost of others. If Regina's husband participates in a culture of son preference, so that he would sacrifice family resources to favor a son when he would not to favor a daughter, his sex-discriminatory preference for cesarean-section delivery may appear less justified.

REFUSAL OF TREATMENT

Case

Thandi, a 19-year-old woman who is unmarried but has a partner, visits a government antenatal clinic, where it is confirmed that she is pregnant. Three out of every ten women who attend public antenatal clinics in the region are HIV-positive. Due to the high prevalence of HIV amongst pregnant women, all women who attend such clinics are routinely tested for HIV and Thandi was tested for the same without her knowledge. On her next visit to the clinic for her follow-up appointment, the attending doctor, Dr Zaku, counseled her before disclosing her HIV status to her. Dr Zaku explains to her that she needs to be treated with ARVs for her own sake and to prevent the risk of her

transmitting the infection to her unborn child during natural childbirth. Thandi refuses treatment because in her society HIV-positive women are ostracized. She requests that her HIV status be kept confidential.

Questions

1. Should Dr Zaku ethically respect Thandi's wishes not to be treated?
2. Can Dr Zaku ethically require that Thandi receive prevention of mother-to-child transmission (PMTCT) treatment against her wishes?
3. Can Dr Zaku ethically give priority to the interests of the fetus/child to be born over those of Thandi?
4. Can Dr Zaku ethically suggest to Thandi that she should terminate the pregnancy?
5. Should Dr Zaku ethically heed Thandi's request for confidentiality?

Assessment

Many people are unaware that they are infected with HIV. Less than 1% of the sexually active urban population in Africa has been tested, and this proportion is even lower in rural populations. Furthermore, only 0.5% of pregnant women attending urban health facilities are counseled, tested, or received their test results. This proportion is even lower in rural health facilities. Based on its sample of 32,861 women attending 1,447 antenatal clinics across all nine provinces, the South African Department of Health Study estimated that 29.4% of pregnant women (aged 15–49) were living with HIV in 2009.

Ethical Analysis

Respect for Persons

Thandi's autonomy regarding refusal of treatment and confidentiality is sound in light of the impending threat of being ostracized

by her family, community, and society in general. However, Dr Zaku has the unenviable task of trying to convince her to take the treatment due to the fact that an estimated 40,000 children in South Africa are infected with HIV each year, reflecting poor PMTCT. Moreover, AIDS is one of the main contributors to South Africa's infant mortality rate, which increased significantly between 1990 (44 deaths per 1,000 infants) and 2008 (48 per 1,000), when all regions of the world saw decreases.

Benefit and Avoidance of Harm

With protection of confidentiality, ARV treatment would be beneficial not only to the fetus/child, but to Thandi as well. The level at which someone begins antiretroviral therapy has a great impact on their chances of responding well to treatment. It needs to be noted that for antiretroviral therapy to work, patients must adhere to a daily regimen of ARVs for life. Interrupting treatment can result in HIV becoming drug resistant, making first-line therapy no longer effective. With high local HIV prevalence and universal precautions, all women are treated as HIV positive, so clinic staffs do not need to know Thandi's HIV status, thus avoiding the harm of disclosure. However, since Thandi has a partner, risk of harm to him necessitates Dr Zaku to advise Thandi that her partner needs to know of her status and the urgency of his being tested for HIV, so that precautionary measures may be taken by her partner in the interim while awaiting his HIV test results.

Justice

The HIV test without Thandi knowing raises ethical issue of whether HIV testing should be routine, and so not specifically mentioned, or whether HIV exceptionalism requires patients to be asked before HIV testing is undertaken? It is to be conceded that HIV is

unlike other infections and ethically different because of the multifaceted impact it has on the family, society, and the country at large. With an estimated 5.6 million people who were living with HIV and AIDS in South Africa in 2009, more than in any other country, justifies implementation of HIV counseling and testing (HCT), which aims to offset the problem of late or no diagnosis. Routine HIV testing and counseling is vitally important in order to make treatment accessible to infected patients. Knowledge of one's positive status can lead to protecting other people from being infected.

REINFIBULATION

Case

When Lina was 11-year-old, her mother submitted her to genital cutting by the most severe form—infibulation. Now aged 22 and married, she has just safely delivered her first child. She has asked the doctor who has attended her throughout her pregnancy and delivery, Dr Ashin, to put her back the way she was by reinfibulation.

Questions

1. Can Dr Ashin ethically simply comply with Lina's request?
2. Should Dr Ashin inform Lina that it is considered unethical for a doctor to undertake infibulation, and refuse?
3. What ethical factors should Dr Ashin consider in deciding on Lina's request?
4. Does Dr Ashin have any ethical duties to Lina's community?

Assessment

The female genital cutting that precedes infibulation is professionally condemned among physicians, and increasingly considered a human rights violation, particularly

when undertaken on young girls incapable of making their own decisions to consent to the procedure. However, legal systems may consider adult and mature adolescent women capable to agree to limited forms of genital surgery, whether for ritualistic or cosmetic purposes. However wrongful initial infibulations may have been, reinfibulation does not involve significant cutting, but resuturing.

A principled professional objection to postnatal reinfibulation is that it may appear to endorse the practice of infibulation, and afford it a degree of medical professional legitimacy and acceptability. That is—medicalization may make female genital cutting appear tolerable. The FIGO 2006 Statement on Female Genital Cutting condemns all forms, but requires that women who have been subjected to any such procedure be treated with sympathy and respect. It further observes that, depending on local laws, "properly informed women who following childbirth, independently request resuturing should not be denied treatment". It is recommended, however, that practitioners explain the benefits of unsuturing and advise against reinfibulation.

Ethical Analysis

Respect for Persons

Dr Ashin's agreement to Lina's request would serve Lina's autonomy, provided that her request is made independently and not pressured by her husband or, for instance, family members. If it were to be seen as medically supporting infibulation, however, compliance with her request might aggravate the vulnerability of young girls in Lina's community to be subjected to dangerous invasive genital cutting. Dr Ashin accordingly has to decide whether Lina's request can be granted while she, her family and community at the same time can be given to understand

that female genital cutting is often a harmful procedure, not required by any religion, and professionally considered unethical.

Benefit and Avoidance of Harm

The contrast between performing a beneficial act and inadvertently contributing to harm, which in this case refers to doing what Lina requests and affirming female genital cutting as a legitimate medical procedure, pitches the microethical values of an individual against macroethical values that serve a community. For Lina to resume her familiar sense of physical identity and integrity after childbirth, as she wishes, would be beneficial for her in a direct way, whereas the harm to her community of medicalizing female genital cutting by reinfibulation would be indirect and speculative. Lina may be advised against resuturing for her own advantage and for the social or communal benefit of opposing female genital cutting as a practice in her region. If she still requires the procedure, however, Dr Ashin must weigh the competing benefits and harms, and their relative likelihood and proximity, in deciding whether to grant Lina's request or leave her to other options she may have.

Justice

Dr Ashin must determine whether reinfibulation is like original infibulation, or different in some ethically relevant way. If the former, Dr Ashin should ethically decline to undertake it, but if the latter, the procedure will not necessarily be as objectionable, and may be undertaken, with due caution to resist legitimation of the prior genital intervention. Laws in some countries differentiate between genital procedures on young girls incapable of consent, and procedures that adult women may request for cosmetic or comparable purposes. Initial cutting presents risks, for

instance of trauma and infection, not present in medically undertaken reinfibulation, which may involve no cutting or minor tissue treatment. As against those contrasting distinctions, however, reinfibulation may be comparable to infibulation in being professionally condemned as an unnecessary medical procedure that is demeaning and harmful to women in general.

SOCIAL SEX SELECTION

Case

Mrs Bee, a 36-year-old mother of two daughters aged 10 and 6, lives in a remote mountain area with her sick 40-year-old husband. Mr and Mrs Bee strongly feel they need a son to support their family, especially in their old age. Mrs Bee comes to see Dr Redil, explaining that she thinks she is now about 12 weeks pregnant. State law prohibits prenatal determination of sex except for a sex-linked genetic disorder. Mrs Bee asks Dr Redil whether she can have a test to determine if the fetus is male or female. Mrs Bee says that she would be willing to continue the pregnancy only if she would have a son. Because of her medical history, state law would allow Mrs Bee to terminate her pregnancy.

Questions

1. Should this case be approached ethically as concerning sex-based abortion or sex-based continuation of pregnancy?
2. Is the ethical duty of Dr Redil only to Mrs Bee, or may societal interests, such as a community sex-ratio imbalance, be taken into account?
3. Is Mrs Bee's request ethically discriminatory?
4. Is it of ethical relevance that, if Mrs Bee is denied prenatal sex diagnosis, she will abort the pregnancy?

Assessment

It is possible to select sex of an embryo or fetus for nonmedical reasons by the same techniques that are usually performed for prevention of sex-linked disabilities, including amniocentesis, chorionic villous sampling, and ultrasound diagnosis. The techniques for sex selection have expanded in recent years, such as sperm separation, preimplantation genetic diagnosis (PGD), embryonic cell biopsy and Y fetal DNA detection in maternal blood by polymerase chain reaction (PCR). These tests are important in medical practice in providing valuable information about genetic abnormalities of the fetus. However, prenatal tests that were developed to detect abnormalities in the fetus have been (mis) used simply for fetal sex selection and sex-based abortion, especially in countries with a culture of son preference.

Ethical Analysis

Respect for Persons

Respect for the autonomy of Mrs Bee would be served by Dr Redil conducting a form of prenatal diagnosis. However, her autonomy may be affected by the legal restriction of prenatal diagnosis of fetal sex, reflecting the common presumption that such diagnosis is intended to result in abortion of female fetuses. Similarly, the FIGO 2005 statement on sex selection for nonmedical purposes allows prenatal sex diagnosis “only for medical indications or purposes that do not contribute to social discrimination on the basis of sex or gender”. This raises the ethical issue of whether, in feeling they can accommodate the birth only of a son, Mrs Bee and her husband are perpetuating social sex discrimination, or whether they are victims of it. This may be because their experience creates their belief that, when old and dependent, they cannot be supported by their grown-up daugh-

ters who, on marriage, are likely to leave the parents’ home.

Benefit and Avoidance of Harm

Son preference is deeply seated in many cultures, especially in China and India. Figures, for instance, from China and South Korea on sex ratios at birth show sex-selected abortion skewing the population toward a dysfunctional preponderance of males. The FIGO 2005 statement on sex selection for nonmedical purposes is designed to eliminate the harm of discrimination. It opens by observing that “the (Ethics) Committee deplores all forms of discrimination against women and the use of any medical techniques in any way that would exacerbate discrimination against either sex. Sex selection is of particular ethical concern when it is driven by value differences ascribed to each sex or that arise from pervasive gender stereotypes.”

Denial of prenatal sex diagnosis to Mrs Bee, however, may also cause harm. Not knowing the fetal sex, she will abort a pregnancy that she would continue, if the fetus was shown to be male. This raises the ethical concern of whether it is preferable that she should have a perhaps unnecessary abortion, or risk perpetuation of sex discrimination for the benefit of continuing gestation of a fetus she knows is male.

Dr Redil faces the ethical dilemma of serving the wider social interest opposing sex-based abortion and harming. Mrs Bee’s intentions to deliver a son, or affording her the benefit of the chance to deliver a son but complying with a sex-discriminatory culture harmful to women.

Justice

The promotion of women’s rights equal to those of men offers the promise to counteract social sex selection against females pervasive

in some areas of the world. All health professionals and their societies are under the obligation to advocate and promote strategies that will encourage and facilitate the achievement of gender and sex equality. However, sex selection against females may be only a symptom, not the cause, of discrimination against women. As an advocate for women's improved status in society, Dr Redil may demonstrate that laws or policies to prohibit sex-based abortion do not address the roots of the problem, and fail to remedy the injustice of pervasive discrimination against girl children and women.

The ethical problem Dr Redil must address in the case of Mrs Bee is whether to resolve it at the clinical (microethical) level, or at a societal (macroethical) level. The former might allow prenatal sex diagnosis under the law, since the law's purpose is to prevent sex-based abortion, not sex-based continuation of pregnancy. Any uncertainty in the scope of prohibitive law is to be decided in favor of individuals' freedom. The latter approach, denying prenatal sex diagnosis, would discount the patient's interests in favor of a wider goal of equality of the sexes and social justice.

SURROGACY

Case

Mrs Abced, 36-year-old, has menorrhagia with a regular cycle, and is extremely anemic. Mother of a 4-year old child, she is also trying to conceive a second child.

Ultrasound assessment of her uterus shows multiple fibroids distorting the uterine cavity. There are two separate indications for myomectomy, the size of her largest fibroid (7 cm), and the distortion by other smaller intramural fibroids. After consultation with her gynecologist, Dr Neutro, she agrees to surgery, aware that there is a chance of hysterectomy. She feels her quality of life is low

and her lack of energy due to anemia is not improved by the usual medication available. She has already thought of surrogacy as an alternative to natural conception. She asks the surgeon to ensure conservation of her ovaries above all other priorities.

The surgeon is unable to conserve the uterus, but otherwise she recovers fully. Her ovarian function is still satisfactory and her husband's semen analysis is normal. 6 months later, she and her husband ask Dr Neutro to help their search for a surrogate to gestate an embryo she and her husband intend to create by IVF.

Questions

1. Can Dr Neutro ethically ask another of the doctor's own patients to serve as a surrogate mother for Mrs and Mr Abced's child?
2. Can Dr Neutro ethically ask a woman with young children of her own to serve as a surrogate mother?
3. Can Dr Neutro ethically attend to Mrs Abced's hormonal stimulation for IVF and also manage the surrogate during her pregnancy?
4. Can Dr Neutro ethically agree to Mr Abced's unmarried and childless sister serving as the surrogate mother?

Assessment

Surrogate motherhood has become accepted as a legitimate reproductive option in many countries, particularly for women who are medically incapable of gestation, but it remains widely subject to legal regulation, for example, of payment. Many countries permit reimbursement of surrogates' out-of-pocket expenses, for instance, but prohibit or tightly regulate reward or gratitude payments. Policies differ, and may conflict, on who may be a surrogate. Some laws provide that only women who have the experience of pregnancy

and childbirth can give informed consent to serve, while in contrast others prohibit women with young children from serving, claiming that young children's care should not be disrupted by their mothers' surrogate pregnancies, and that children might feel insecure to realize that their mothers would give away their babies.

This case involves "full" surrogacy, meaning that the surrogate mother would be genetically unrelated to the child she delivers. In contrast would be "partial" surrogacy, in which the surrogate would gestate her own egg, fertilized artificially by Mr Abced's or another man's sperm, without IVF. The difference can affect legal recognition of who are the "real" parents of a newborn child.

Ethical Analysis

Respect for Persons

Although legally restricted in some European countries, surrogacy enhances a reproductively impaired couple's autonomy by giving them the choice to have a child genetically related to both or at least one of them. The surrogate mother's autonomy may be severely prejudiced, however, and her vulnerability exploited, if she comes under family or comparable pressure to serve. She may be similarly vulnerable, if poverty tempts her to agree to serve under the promise of lawful or unlawful payment. However, compensation for pregnancy-related expenses and loss of actual income is generally considered ethically acceptable, and perhaps necessary. Some women take pleasure and pride as surrogate mothers in giving other couples the gifts of their babies' lives, but they should not ethically be required to subsidize their gesture.

Pregnant women generally accept limits to their autonomy for the sake of their fetuses, such as regarding their diets and alcohol and/

or tobacco use. They may also accept antenatal screening, which may lead to hard decisions on detection of fetal anomalies and/or maternal health risks. On these occasions, the autonomy of surrogate mothers and of intended parents may conflict.

Benefit and Avoidance of Harm

When surrogate motherhood agreements work satisfactorily, receiving parents, surrogate mothers and societies benefit, although to what comparative advantage is difficult to quantify. If relationships among participants should sour, agonizing emotional, and legal, results may follow. However, even in the most favorable of circumstances, pregnancy involves unavoidable risks to mothers' health and very lives. No country has zero maternal mortality. For Mrs Abced, there are irreducible minimum risks, perhaps of OHSS, and of oocyte retrieval for IVF. It is therefore essential that all prospective participants receive disinterested counseling about their individual risks. Potential surrogate mothers should be relatively young, physically healthy, and psychologically able to accept the implications of surrendering the babies they have gestated. Single embryo transfer is advisable, in order to avoid the risks of multiple pregnancy, the most common complication of IVF.

Justice

There may be a risk of social injustice, if practitioners dedicate disproportionate time to surrogacy arrangements, perhaps because of their complexity or income generation, where there is a general lack of adequate routine antenatal care for their local populations. A more particular injustice may arise, if poor and/or unemployable women are induced to accept the burdens and risks of surrogate pregnancy for payments, which themselves may be exploitatively low. A comparable

challenge to justice might arise, if women capable of healthy gestation were to recruit paid surrogates to gestate their children, so that they could avoid stretch marks, inconvenience, or, for instance, career disruption. Laws that unduly complicate recognition of children's legal parentage, when surrogate motherhood agreements are entered in good faith and work to all participants' satisfaction, require ethical reform.

TASK SHIFTING AND MATERNAL MORTALITY

Case

Fatoumata is 15-year-old. She was married the previous year and soon became pregnant. Her village is 100 miles from any urban medical center. In her community, pregnancy is considered a natural event, with no necessity, or capacity, for a physician's care. The only persons caring for pregnant women and attending delivery in this rural community are the matrons, the TBAs. All pregnant women in Fatoumata's family, and community, have been delivered by matrons. One of her aunts and an elder sister died during delivery. An emergency care facility has now been installed in a nearby village. The health professional in the facility is not a physician, but a male nurse, a health officer, practicing after 3 years of specialized training. Fatoumata has been in labor for 2 days, is bleeding from the uterus, and complaining of insufferable pain. The matron perceives no progress in labor, the uterine cervix being only two fingers dilated after 2 days of regular, painful, uterine contractions, and the head of the baby is still very high in the pelvis.

The matron knows there is now the need for a cesarean section to prevent the likely death of Fatoumata and her baby from a rupture of her uterus. Her family is too poor to hire an ambulance for her transfer to a city

medical center and to pay for the surgical procedure. Cesarean section for Fatoumata is the only life-saving procedure. Only the local health officer is able to attempt a cesarean section.

Questions

1. Is it ethically preferable to let the health officer give Fatoumata, and her baby, a chance of survival by performing a cesarean section in this emergency medical setting?
2. Is it better to let the natural process of birthing give Fatoumata a chance of delivering naturally, without the risk of surgical, and perhaps fatal, complications occurring during cesarean section performed by a nonsurgeon?

Assessment

Every year, an estimated 450,000 women, exceeding one every one and a half minutes, die because they are pregnant. The major cause of maternal death is postpartum hemorrhage or hemorrhage due to obstructed labor and uterine rupture. Of all maternal deaths, 99% occur in resource-poor countries where women deliver at home, far away from any emergency obstetrical center. The main reason for maternal death is poverty. The lack of birth professionals attending home delivery induces a delay in the recognition of obstructed labor (TBAs are not properly trained birth professionals). Poverty explains inability to hire an ambulance to reach a properly equipped urban emergency obstetrical center and to pay for emergency obstetrical care. Neither surgeons nor obstetricians usually practice in isolated rural areas. The rate of emergency cesarean section needed to save maternal lives is considered to be at least 3% of all deliveries. Where there is no doctor,

the choice is either to leave the woman in the care of nature, with an extremely high risk of death, or to have a nonphysician perform the cesarean section. Indeed several countries in Africa, Mozambique, and Ethiopia among others have given male nurses or health officers 3 years' training to perform cesarean sections when necessary. The immediate operative complication rate is no higher than when the procedure is performed by physicians. However, the indications for cesarean section and the long-term complications, such as postsurgery vesicovaginal fistulas, have not yet been properly evaluated.

Ethical Analysis

Respect for Persons

Fatoumata has little opportunity for autonomy, since she is vulnerable to her poverty and the deprivations of her location. However, she may choose whether to attempt relief of her pain by treatment performed by the health officer.

“Obstetric professional societies should publicize the tragedy of maternal mortality as a violation of women’s rights” (FIGO Recommendation on Safe Motherhood).

Benefit and Avoidance of Harm

If cesarean section performed by a nonphysician happened to be worse, and more deleterious, than no surgical procedure at all, then task shifting would be unethical. In fact, where implemented, the benefit of such policy appears to surpass any potential immediate harm inflicted to the pregnant woman. The risk of death from a cesarean section performed by a nonphysician is far below the unavoidable risk of death from uterine rupture, and between the two harms, it is preferable to choose the lesser.

Justice

Maternal death is mostly a consequence of poverty. The burden and hardship of poverty can be partly alleviated by making free all emergency obstetrical care, as advocated by the World Health Organization. It should include, for any rural community—available free transportation to properly equipped emergency care centers, roads practicable for vehicles, including during the rainy season, in addition to the training of an adequate number of skilled birth professionals, particularly health officers who, in application of task shifting, are able to perform all emergency obstetrical care, especially cesarean sections. Since the level of education of girls and the fertility rate have been shown to significantly influence maternal mortality, distributive justice also implies appropriate investments of governmental and health authorities in the development of schools for girls and of family planning centers.

TERMINATION OF ADOLESCENT PREGNANCY

Case

Ella, an adolescent 18 years of age, visited Dr Abco with a concern about missing her period. Her family is religiously conservative and known to the physician. She had a sexual encounter with a visiting family friend while he lived in the same house. After examining Ella, Dr Abco informed her that she was 10 weeks pregnant. Ella was shocked and pleaded with Dr Abco to do whatever was necessary to terminate this unwanted pregnancy. The physician was very angry with Ella and admonished her, refusing to help her unless she came back with her parents to discuss any further action. Ella had been brought up in a culture that looked down upon girls engaging in premarital sex. Hence, she has

had no access to information on normal reproductive function, let alone contraception, either through her family, or through the local school.

Dr Abco informed her that she would have to undergo a termination of pregnancy, if she did not wish to continue the pregnancy. Under local laws, carrying out an abortion is legal and within her right to consent at 18 years of age, but the doctor insisted that Ella get her parents to come to Dr Abco's office before the procedure could be conducted. Ella's doctor feels conflicted because of knowing the parents and being concerned about potential complications that would make performance of an abortion on their daughter known to them, but also concerned about their being unaware of the circumstances that allowed a visitor to engage in sex with their daughter.

Questions

1. Was Dr Abco's behavior toward Ella ethically right?
2. Does the doctor have an ethical obligation to disclose Ella's request to her parents?
3. Does the doctor have to seek consent for abortion from Ella's parents even though it is legal to perform an abortion without parental consent after the patient is 18-year old in that country?
4. Should Dr Abco perform a safe abortion for Ella rather than leave her to go to an unskilled provider, which could endanger her life, fertility, or health?

Assessment

Doctors' primary ethical duties are owed to their patients, and they discharge such duties by addressing not only patients' medical conditions but also their health conditions, understood by the World Health Organization to include their "physical, mental, and social well-being". Accordingly, patients'

family and social circumstances have to be taken into account. Unmarried adolescents' pregnancies will be sources of severe prejudice to them in many family and social settings, denying them for instance future opportunities of education, employment, and marriage, and perhaps of rearing the children they deliver. Where lawful, termination of pregnancy by medically conducted or regulated means may best serve the interests of unmarried adolescents who give their free and adequately informed consent.

Ethical Analysis

Respect of Persons

Since Ella has requested an abortion that Dr Abco is lawfully entitled to undertake, the doctor may comply with her request or refer her to another doctor able and willing to undertake the procedure. Dr Abco should question Ella about whether her parents should be informed, the likelihood of them discovering it if they are not informed, and whether it is feasible for her to pursue her goals in life, if she chooses to continue the pregnancy. Compliance with her decision should not be made conditional on Ella informing her parents of her pregnancy, although they may be informed that she requires a gynecological procedure. Ella's autonomy entitles her to control not only any healthcare procedure she undergoes, but also who may receive information that it would violate her confidentiality to disclose without her consent.

Benefit and Avoidance of Harm

By complying with Ella's adequately informed decisions on abortion and confidentiality, Dr Abco is acting beneficially. Abortion carries a medically lower risk of complications and death than carrying a pregnancy to term, particularly for young women. Performance

of abortion by appropriate means related to the stage of gestation, in a well-maintained clinical setting, will minimize risks to the patient, and save her from an unskilled intervention, including the risks of self-induced abortion. Potential harms of unskilled intervention include hemorrhage, infection, infertility, and death.

Dr Abco should not be judgmental or condemnatory, but should provide Ella with contraceptive advice following termination of pregnancy, and guidance on means to resist unwanted sexual advances, including by involvement of her parents. Dr Abco should also be attentive to Ella being depressed due to her unwanted pregnancy, conflict with her religious or spiritual values, and the implications for her of the circumstances in which she finds herself.

Justice

Dr Abco affords Ella her rights by providing necessary counseling, advising her of choices lawfully available to her, and by facilitating the outcome she favors. At a wider level, Dr Abco may advocate for adolescents' access to reproductive and sexual healthcare education and means. The doctor may also urge parents to be aware of their adolescent children's growing sexuality and liability to sexual curiosity, and their need for guidance, without parents overprotectively denying them opportunities for healthy growth and experience of appropriate social interactions.

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Appendix: Instructors' Guide

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The purposes of the International Federation of Gynecology and Obstetrics (FIGO) Introduction to Principles and Practice of Bioethics are to make medical students of obstetrics and gynecology, and interested practitioners, aware of key concepts in bioethics, and to provide them with some case studies to acquire some early experience in their application.

Students are expected to review the case studies, supplemented by further real-life cases drawn from their own developing experience, in light of key ethical principles. They should identify principles that they consider relevant to a case study, the level at which they find that principles should be applied, and the priority that should be given to principles in order to make one more relevant to any other to ethical decision making.

The case studies are not designed to have “right” answers. We learn as much from errors as from making “right” decisions, and we learn from our own errors as well as from those we perceive our colleagues to make. Students must therefore be given opportunities to make choices that others, including their instructors, consider ethically flawed or indefensible. Instructors must not initially direct or unconsciously guide students to make what seem to be acceptable decisions. Some options presented in the case study questions appear to be misguided, but it is for students to reach their own conclusions. Only after students have reached their own conclusions should they be further questioned in order to expose any flaws or concerns that may arise in their ethical reasoning. They must at first be allowed to make errors, in order for instructors to explain the points in their reasoning at which errors have arisen.

They should be required to explain and justify their proposed decisions in terms of the ethical values they find to be at stake, explain why they consider others' different perceptions and priority of values to be less preferable than their own, and respond to points that instructors raise to test whether their reasoning and conclusions can bear the weight of ethical examination.

Students should not feel bound to change their conclusions on cases simply because they find ‘classmates or instructors’ different conclusions to have an ethical foundation. There may be more than a single ethically acceptable resolution to a question raised in a case study, and in a real-life situation. Students should aim to reach and justify resolutions that they find ethically appropriate, even while recognizing that other resolutions, giving priority to competing principles or a different level of approach, may also be ethically defensible.

Instructors should try to contain consideration of the case studies to the simple fact patterns in which they are framed, and not allow students to develop additional facts that permit resolutions of cases on medical, social, scientific, or other grounds that evade the students having to come to grips with their ethical aspects. In real-life circumstances, there may indeed be strategies that relieve ethical dilemmas, such as increasing supplies of resources or bringing in additional personnel, but in addressing the case studies, the ethical issues should be addressed on their own terms and not be avoided by technical additions of facts. Within the terms of a case study, however, students should be allowed and encouraged to find additional ethical questions and options for resolution that merit attention.

Index

A

- Abortion 65, 139
 - Act 72
 - anencephaly and late-term 113
 - direct 65
 - induced 6
 - medical monopoly of 73
 - of female fetuses 146
 - procedures 62, 66
 - related information 75
- Accreditation Council for Continuing Medical Education 85
- Acquired immunodeficiency syndrome
 - disease 10
 - management of 16
- Adolescent pregnancy, termination of 150
- American College of Obstetricians and Gynecologists 20, 141
- Antenatal
 - care 115
 - period 25
 - screen, part of 14
- Anti-Mullerian hormone 126
- Antiretroviral therapy 129
- treatment 14
- Autonomy, principles of 57

B

- Bioethical analysis 101
- Bioethics and faith-based organizations 117
- Body fluids, pathways of 37

- Brain death, determination of 43
- British Medical Journal 133
- Burden of disease 10

C

- Cardiac
 - function 43
 - malformation, severe 115
 - resuscitation initiatives 43
- Cardiotocography 25
- Cervical cancer 132, 133
- Cesarean section 21, 218
 - delivery 142
 - refusal of 141
- Chronic disease 17
- Club foot, bilateral 115
- Compact disk read-only memory 24
- Computed tomography 125
- Consent, effectiveness of 21
- Constitutional court 65
- Continuing medical education 83, 84
- Crime, essential elements of 90
- Criminal
 - actions 95
 - justice system 94, 95
 - law, purpose of 90
 - medical negligence 91, 95
 - negligence, criminal court consists of 91
 - prosecution, proponents of 94
- Criminalization 90

D

- Dermoid cyst 128
- Dichotomous fashion 21

- Diverting controlled substances 89
- Donation
 - live-related 36
 - live-unrelated 39
- Donor's less mercenary 40
- Doubting rape 65
- Down's syndrome 115

E

- Egg donation 126
- Ella's autonomy 151
- Embryo 125
 - cryopreservation 45
- Estrogen pregnancy prophylaxis 68
- Ethical
 - elements, discussion of 109
 - issues 10
 - justification 7
- Ethics
 - education 99
 - principles 103
- European Committee of Social Rights 67
- European Court of Human Rights 69
- European Social Charter 67
- Euthanasia 89
- Eve's newborn 131

F

- Family planning 112
- Female genital
 - cutting 128, 144
 - risks 129
 - mutilation 128
- Female sterilization 136
 - involuntary 136

Fetus 3, 5, 65, 125
ethical concept of 3, 6

H

Health facility administrators 76
Health policy

and clinical practice,
intersection of 53
challenges 95

Healthcare

business operations 89
institutions 66
services, public provision of
120
system 93

Hepatitis B 130

immunoglobulin 131
vaccination 129
vaccine 131

Highly active antiretroviral
treatment 10

Hippocratic medical ethics 3

Home birth

choice of 120
planned 7

Human immunodeficiency

virus 10, 11, 14, 16, 108
counseling 144
disease 10
in pregnancy 13
infected women,
reproductive rights of 12
infection 16, 17
management of 16
positive 130
status 16
test 14, 17, 143, 144

Human medical biology 102

Human papillomavirus 108

vaccination 131, 132
vaccine 105

Human reproduction

and women's health 110
ethical aspects of 136

Human rights 101, 127
principles 65
violation 144

Human tissue authority 40

Hysterectomy 133
abdominal 133

I

Immunity, governmental grants
of 77

In vitro fertilization 34, 127

Infertility 33
global incidence of 33

Intensive care unit 12

International Federation of
Gynecology and
Obstetrics 20, 59, 81,
95, 109

Intracytoplasmic sperm
injection 138

Intrafamilial surrogate
motherhood 38

Intrapartum management 7

Intrauterine devices, insertion
of 76

J

Justification, criminalization
bears burden of 92

L

Labor after cesarean, trial of 8

M

Maternal
complications 121
fetal intervention 7
mortality 126

Mayer-Rokitansky-Küster-
Hauser syndrome 33

Medical errors, criminalization
of 89

Medical licensing boards 85

Medical monopoly 72

Medical negligence 90
essential components of 90
issues of 90

Medical profession, integrity
of 95

Medical professionalism 60

Medicus politicus 4

Megaethical level 105

Mila's maturity 111

Mind, culpable state of 91

Miscarriage, spontaneous 66, 73

Multiple pregnancy 137

N

National Health Service 77

Negligence

assessing criminalization of
92

assessment of
criminalization of 95
occurrence of 91

Neonatal complications 121

New medication delivery system
84

O

Obstetric fistula 139

Obstetricians and
gynecologists,
professional practice
of 55

Obstructed labor, recognition
of 149

Organs

donation, cadaveric 39
removal of 43

Ovarian hyperstimulation
syndrome 127

Ovum retrieval 127

P

Paid uterus donation,
prohibition of 42

Patricia's treatment 112

Placenta 65
 previa, intrapartum complete 8
 Pluralistic populations 118
 Polymerase chain reaction 146
 Precancerous disorders 37
 Preeclampsia 36
 Pregnancy 115
 and venereal infection, diagnosis of 65
 high-risk 25
 normal 115
 previsible 6
 Preindictment screening panels 95
 Prima facie 6, 9
 Professional negligence 91

R

Rectovaginal fistula 139
 Regina's self-determination 141
 Registered medical practitioner 72
 Reinfibulation 144
 Repeat-back technique 24
 Reproductive physiology 33
 Rh isoimmunization 3

Roman catholic tradition 70
 Routine antenatal care, part of 25
 Royal College of Obstetricians and Gynaecologists 19

S

Sexual and reproductive health 55
 services 55, 58
 rights 55, 56, 60
 Sexual transmission 130
 Short-nasal bones 115
 Single embryo transfer 138
 Society of Obstetricians and Gynaecologists of Canada 58
 Sperm separation 146
 Stigmatization 15
 Surrogacy 147
 Sympathy 5
 System errors 93

T

Traditional birth attendant 139
 Transplantation, wombs for 44

U

Universal Declaration of Human Rights 101
 Uterine cervix 115
 factor infertility 34
 graft, advantage of 44
 transplantation 33, 36
 Uterus
 donors 40
 recipients 45
 transplantation 35, 47, 48
 goals of 47

V

Vertical transmission, risk of 10
 Vesicovaginal fistula 139
 Violations, criminal prosecutions for 89

W

Women lawful abortion 65
 World Health Organization 33, 150
 World Medical Association's Modern Hippocratic Oath 63