ETHICAL ISSUES IN OBSTETRICS AND GYNECOLOGY
by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women’s Health

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FOREWORD

Obstetrics and Gynecology, as it deals with all of life’s major passages – birth, reproduction, aging, and death – has seen every major medical advance create unexpected ethical dilemmas for our discipline. The moral dilemmas that face Obstetrics and Gynecology range from public advocacy for the very basic needs of health and human rights for women to the most intricate issues surrounding the growing knowledge and use of the human genome.

In 1985 FIGO set up the Committee for the Study of Ethics in Human Reproduction and Women’s Health. The main objectives of the Committee focus on recording and studying the general ethical problems which emanate from research and practice in women’s health as well as bringing these issues to the attention of physicians and the public in developed and developing countries. From the time of its inception, the Committee has made recommendations for the guidance and to stimulate discussion for all practitioners, and particularly for use by member societies to stimulate broader national and regional discussions on vexing ethical issues.

All of the recommendations may be published, translated and circulated provided the initial explicable introduction is included (see page 7) and due acknowledgement is given. There is no copyright against publication.

Gamal I. Serour

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FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health

Committee Statement to be used when publishing the enclosed Ethical Guidelines

Introduction

The FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health considers the ethical aspects of issues that impact the discipline of Obstetrics, Gynecology and Women’s Health. The following documents represent the result of that carefully researched and considered discussion. This material is intended to provide material for consideration and debate about these ethical aspects of our discipline for member organizations and their constituent membership.
1. Obstetricians-Gynecologists have an ethical duty to be advocates for women’s health care. As members of a learned profession, they have a body of knowledge that includes sexual and reproductive health. They are usually the first professional that women approach with health problems in this area. They therefore have a duty to provide care based on this knowledge and experience. The knowledge base and social standing of physicians places them in a position with the potential to influence policies regarding women’s health.

2. This obligation is increased by the unique vulnerability of women because of their reproductive function and role. Social discrimination and abuse based on gendered undervaluing of women may further compromise women’s health. Concern for family welfare may take precedence over individual health and also increase their health risks.

3. Sexual and reproductive health and access to health care for women are influenced unjustly by unequal exposure to violence, poverty, malnutrition and by denied opportunities for education or employment. This obligates the obstetrician-gynecologist to advocate improvement of the social status of women.

4. Obstetricians and gynecologists are obliged individually and as a profession to monitor and publicise indices of reproductive health and provide data to sensitise the public to health issues and rights of women. The informative function should not be limited to quantifying the problem, but they should also identify the social and cultural causes in their own countries in order to develop appropriate strategies for the improvement of the present situation.

5. Failure to advocate policies that will improve women’s health care and advance women’s rights broadly will deleteriously influence the health care of the individual patient cared for by the ob/gyn.

6. Obstetricians and gynecologists should inform the community about the problems of sexual and reproductive health and promote a wide
debate in order to influence health practices and legislation. The debate should include a broad spectrum of society, such as other medical associations, women’s organisations, legislators, educators, lawyers, social scientists and theologians. In addition, obstetrician/gynecologists are obligated to organise themselves and other professional groups to ensure that essential health services are available for disadvantaged and underprivileged women.

London, April 1999

VIOLENCE AGAINST WOMEN

1. Violence against women is multi-faceted and reflects the unequal power relationship of men and women in virtually all societies. Enforced marriage or marriage at a very young age, lack of information or choice about fertility control, lack of education or employment opportunities, and lack of choice about pregnancy within marriage are forms of coercion that result from unequal power relationships and set up environments that aggravate the risk of violence against women.

2. Violence against women is condemned, whether it occurs in a societal setting (such as female genital mutilation) or a domestic setting (such as spousal abuse). It is not a private or family matter. Violence against women is not acceptable whatever the setting, and therefore physicians treating women are ethically obligated to:

   (i) Inform themselves about the manifestations of physical, social and psychological violence, and learn to recognise cases. Documentation must take into account the need for confidentiality to avoid potential harmful consequences for the woman, which may require separate, non-identifiable compilation of data.

   (ii) Treat the physical and psychological results of the violence.

   (iii) Affirm to their patients that violent acts towards them are not acceptable.

   (iv) Advocate for social infrastructures to provide women the choice of seeking secure refuge and ongoing counselling.

3. The physical, financial and social vulnerabilities of women are
fundamentally harmful to the future of any society. Not redressing them fails to prevent harm to subsequent generations, and contributes to continuing the cycle of violence. Physicians treating women therefore have an obligation to:

(i) Affirm women’s right to be free of physical and psychological violence, including sexual violence, examples of which range from war crimes in conflicts between and within states to sexual intercourse without consent within marriage, honour killings and sex selection.

(ii) Advocate for non-violent resolutions of conflicts in relationships by enlisting the aid of social workers and other health care workers where appropriate.

(iii) Make themselves, and others, aware of the harmful effects of the embedded discrimination against women in social systems.

4. There is a need for wider awareness of the magnitude of the problem of violence against women. Only if this problem is recognised can it be addressed. Physicians, as advocates for women, are uniquely placed to assist in this. There is therefore a duty for professional societies and physicians to publicize information about the frequency of types of violence against women, and the implications for the wider society of allowing this to continue.

*Lyon, June 2007*

**SEX SELECTION FOR NON-MEDICAL PURPOSES**

**Preamble**

1. The international context of sex selection is grounded in a setting where the majority of women are disadvantaged in enjoyment of economic, social, educational, health, and other rights. The global impact of the desire to achieve sex selection has resulted in systematic rights abuses such as selective abortion of female fetuses, female infanticide, neglect of girl children and failure to provide either access to or support for health care of girls. This has led to a global imbalance of variable intensity in the sex composition of populations.

2. The Committees deplore all forms of discrimination against women
and the use of any medical techniques in any way that would exacerbate discrimination against either sex.

3. 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.

4. In viewing medical and scientific association guidelines throughout the world, common ethical issues raised include concerns about the selection for children with presumed gender characteristics desired by their parents rather than being an end in and of themselves.

5. Legal approaches to sex selection for non-medical reasons vary by country and range from no specific regulation of this issue to complete prohibition and criminalization.

Present Technology

1. It is possible to select the sex of an embryo or fetus for non-medical reasons by the same techniques that are usually performed for prevention of sex linked disabilities.

2. The techniques for sex selection have expanded throughout preconception and postconception. Preconception sex selection includes sperm separation. Pre implantation genetic diagnosis (PGD) necessitates in vitro fertilization and embryonic cell biopsy. After implantation is established, Y fetal DNA can be identified in maternal blood by polymerase chain reaction (PCR). Chorionic villous sampling (CVS), amniocentesis or echography are additional means that can identify fetal sex.

Guidelines

1. The use of sex selection to avoid sex linked genetic disabilities is generally considered justifiable on medical grounds.

2. Because sperm separation and PGD avoid termination of an ongoing pregnancy, they may appear to be less objectionable techniques for non-medical sex selection. However, since they can also result in gender discrimination, in this respect they are not ethically different from those means used in ongoing pregnancy.
3. Professional societies must ensure that their members and their members’ staff are accountable for the employment of techniques for sex selection only for medical indications or purposes that do not contribute to social discrimination on the basis of sex or gender.

4. Where a regional area has a marked sex ratio imbalance, the professional societies should work with their governments to ensure that sex selection is strictly regulated to contribute to the elimination of sex and gender discrimination.

5. Procreative liberty warrants protection, except when its exercise results in sex discrimination. The individual right to procreative liberty needs to be balanced by the communal need to protect the dignity and equality of women and children.

6. Irrespective of the approach to non-medical sex selection, all health professionals and their societies are under an obligation to advocate and promote strategies that will encourage and facilitate the achievement of gender and sex equality.

London, March 2005

ETHICAL FRAMEWORK FOR GYNECOLOGIC AND OBSTETRIC CARE

1. Women tend to be vulnerable because of social, cultural and economic circumstances. This is the case within the doctor-patient relationship, because in the past women’s care has often been dominated by the paternalism of their advisors.

2. The principle of autonomy emphasizes the important role women should play in decision-making in respect to their health care. Physicians should try to redress women’s vulnerability by expressly seeking women’s choices and respecting their views.

3. When decisions regarding medical care are required, women should be provided with full information on available management alternatives including risks and benefits. Informing women and obtaining their input and consent, or dissent, should be a continuing process.
4. Because of the intimate personal nature of obstetric and gynecologic care, there is a special need to protect patient confidentiality.

5. In addition to the provision of medical services, physicians have a responsibility to consider women’s well-being and psychological satisfaction with their gynecologic and obstetric care.

6. In the delivery of health care to women, justice requires that all be treated with equal consideration, irrespective of their socioeconomic status.

7. If a physician is either unable or unwilling to provide a desired medical service for non-medical reasons, he or she should make every effort to achieve appropriate referral.

8. Ob/gyns should address barriers to women’s health care and services, including barriers due to social discrimination against and devaluation of women.

9. Ob/gyns should ensure that policies that affect the direct care of women’s health are based on best available evidence.

10. Ob/gyns should act as advocates for fair and affordable access to women’s health services, in particular regard to women’s sexual health, irrespective of a woman’s age, marital, racial, ethnic, socio-economic or religious status.

Reference: The Role of the Ob/gyn as an Advocate for Women’s Health page (8) and Ethical Guidelines on Conscientious Objection page (25) of the Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women’s Health, October 2012.

Lyon, June 2007

GUIDELINES REGARDING INFORMED CONSENT

1. The obligation to obtain the informed consent of a woman before any medical intervention is undertaken on her derives from respect for her fundamental human rights. These rights have been widely agreed on and are laid down in such documents as the Universal Declaration of Human Rights (1948); the twin International Covenants on Civil and Political Rights and Economic, Social and Cultural Rights (1975);

2. The following definition1 of informed consent flows from these human rights and is endorsed by the FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women’s Health:

“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:

a) the diagnostic assessment;

b) the purpose, method, likely duration and expected benefit of the proposed treatment;

c) alternative modes of treatment, including those less intrusive, and

d) possible pain or discomfort, risks and side effects of the proposed treatment.”

3. Although these criteria are clear, to implement them may be difficult and time consuming, for example where women have little education, or where very unequal power relationships in a society mitigate against women’s self-determination. Nevertheless, these difficulties do not absolve physicians caring for women from pursuing fulfilment of these criteria for informed consent. Only the woman patient can decide if the benefits to her of a procedure are worth the risks and discomfort she may undergo. Even if, for example, other family members feel they should make the decision, it is the ethical obligation of the physician to ensure that the woman’s human right of self-determination is met by the process of communication that precedes any informed consent.

4. Consent can be withdrawn at any time.
5. It is important to keep in mind that informed consent is not a signature, but a process of communication and interaction.

6. The opinion of children or adolescents on a medical intervention should be assessed within the limitations posed by their level of development or understanding.

7. Even if a woman is unable to decide for herself because of mental incapacity or mental retardation, nevertheless she must be involved in the decision-making process to the fullest extent her capacity allows, and her best interests must be taken into account.

8. If physicians, for reason of their own religious or other beliefs, do not wish to fulfil the above criteria for informed consent because they do not want to give information on some alternatives, they have an ethical obligation, as a matter of respect for their patients’ human rights, to disclose their objection, and to make appropriate referrals so that the patients may obtain the full information necessary to make valid choices.

Note 1. UN Resolution on Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care 11.2.

Lyon, June 2007

THE ETHICAL ASPECTS OF SEXUAL AND REPRODUCTIVE RIGHTS

Sexual and reproductive rights of individuals are essential components of human rights. They should never be transferred, renounced, or denied for any reason based on sex, race, age, language, religion, national origin, political opinion or economic condition. For women within the health care system, and particularly within the care offered by obstetricians and gynecologists, this statement of human sexual and reproductive rights implies certain ethical imperatives;

1. Women and men have a right to the highest available standard of health care for all aspects of their sexual and reproductive health. This includes access to adequate, accurate and relevant information. Governments have a responsibility to ensure that improvements in sexual and reproductive health have a high priority.
2. Women and men have the right to decide matters related to their own sexuality. The decision to have or not have sexual relationships should be free of coercion, discrimination and violence.

3. Women and men have the right to make choices with their partners about whether or not to reproduce.

4. Women and men need to have access to legal, safe, effective, affordable, and acceptable methods of fertility regulation consistent with their choices.

5. Women and men have a right to bodily integrity. Medically harmful mutilation of body parts associated with gender or sexual function such as female genital mutilation is ethically unacceptable.

**Basle, 1997**

**SOME ETHICAL ISSUES IN THE DOCTOR/PATIENT RELATIONSHIP**

1. Maintenance of strict boundaries in the relationship between patients and physicians is required because of the inherent imbalance in power and knowledge between them. This imbalance increases patients’ vulnerability so that there is a concomitant obligation on the part of physicians to promote independent and informed decision-making by patients. Violation of boundaries in the relationship destroys the trust essential to the health care and healing process.

2. For the above reasons, a romantic or sexual relationship is unacceptable at all times and in all circumstances between a physician actively treating a patient and the patient.

3. A sexual or romantic relationship distant from an active physician/patient relationship is acceptable only if no residual dependency exists on the part of the patient.

4. Other boundary violations that can occur because of the power imbalance include requests for financial advice, benefit or influence on decisions outside the health care context. All of these have the potential of crossing boundaries inappropriately.
5. For financial issues such as donations or fund-raising from patients or their families, involvement of disinterested third parties is desirable to ensure that any donation is freely chosen and not influenced by dependency.

_Basle, 1997_

**ETHICAL GUIDELINES IN REGARD TO TERMINALLY ILL WOMEN**

1. Obstetrician-Gynecologists may be involved in the care of women where death of the patient is inevitable.

2. The health-care giver must clarify what goals of medicine can be met in the terminal phase of illness, such as relief of suffering and pain and the maximisation of comfort. These factors take precedence when the goals of cure or remission are no longer obtainable.

3. The transition from curative to palliative care may require the primary involvement of physicians with special knowledge of palliative care. However, the obstetrician-gynecologist should continue his or her supportive role for the patient and her family.

4. The expressed choices of the woman regarding life support must be carefully discussed. The choice not to attempt resuscitation must be revisited with the patient as the circumstances of the disease process change, even in the face of a prior advance directive. This discussion requires the physician to guard against his or her own social and cultural biases in presenting the issues to the patient.

5. The presence of an advance directive such as a “Do not resuscitate” order does not remove the physician’s obligation to ensure maximal palliative care at the end of life including adequate pain control.

6. Advocacy for adequate terminal care is an important role for women’s health care providers. The indignities of impoverishment are more common in women of all ages. They are linked to lack of access to adequate end-of-life care at home or in hospital.

7. The patient’s care should take into account the unequal power relationship between men and women, in order to ensure respect for
the right of a woman to make her own choices at the end of life. Any social coercion or discrimination based on gender that might lessen the quality of care, coming from the family or the health care provider, must be avoided.

8. A dying woman who is pregnant may face choices between achieving maximal palliative care for her condition or achieving maximal fetal welfare. This choice requires the physician to provide balanced and unbiased clinical information regarding the benefits and harms of all the potential options for the woman herself as well as for the potential fetal outcome.¹

9. Death is part of the cycle of life in a community. The death of an individual involves close family members and friends in an intensely emotional and important event. Bearing in mind the over-riding wishes of the dying woman, every effort should be made not to exclude family and friends from the dying process.

10. When a dying woman prefers to die at home, every effort should be made within the practicality of the situation, medical or social, to comply with her wish and to maintain good palliative care in that environment.

11. Women are particularly vulnerable to suffer inadequate access to optimum pain management by virtue of poverty and low social status. In addition, they may be concerned that the cost of adequate pain relief may further impoverish their families. These factors may influence women to look for ways, such as assisted suicide or active euthanasia, to end their lives. The use of drugs or other means whose primary purpose is to relieve suffering and pain may be regarded as ethical, even though they may shorten life. Their use to deliberately cause death is ethically unacceptable.

*London, April 1999*

¹ See Ethical Guidelines regarding Interventions for Fetal Well Being.
CONFIDENTIALITY, PRIVACY AND SECURITY OF PATIENTS’ HEALTH CARE INFORMATION

Background

Since antiquity, physicians have been professionally obligated to keep to themselves “what I may see or hear in the course of treatment”. Two intertwined concepts, confidentiality and privacy, are critically important to the sensitive issues addressed in the course of health care for women. Privacy has a broader conceptual framework that encompasses decisional, physical, and informational privacy. Decisional privacy affirms the human right to make choices, particularly in health care, without the intervention of others or the state, and supports autonomy. Physical privacy affirms the right to allow or deny providers the right to examine or treat, but even if permission is given, it still requires careful protection from unnecessary or embarrassing bodily contact or exposure. Informational privacy underpins the issues of confidentiality in medical care, and is the most critical element of these ethical obligations, particularly in environments with computer access, insurer access, governmental access, and multiple health provider access to patient records.

Women are particularly vulnerable to personal harm or discrimination from breaches in medical confidentiality, particularly in those circumstances where domestic violence, sexually transmitted diseases or predisposition testing is involved. Because of their greater risks from breaches in confidentiality, the obligation to ensure strict confidentiality in women’s health care is greater for health professionals.

Modern principles of data protection have been recognised as having important implications for the proper storage, management and processing of personal data. These principles require:

• that data shall be accurate and up to date
• that stored data should be adequate, relevant and not excessive
• that data is available to the patient to verify factual accuracy,
• that data is processed fairly and lawfully;
• that data is not stored for longer than will serve the interests of the patient; and.
• that data protection shall include
  (i) security against improper access;
(ii) prompt access to serve the interests of the patient; and
(iii) security against accidental loss or destruction.

Medical information obtained in the care of patients is essential for the care of the individual as well as for improvement of health care services, public health, and the advancement of research in health care. Sharing information in the context of the health care team for the individual or with a parent or guardian if the patient is a minor or incompetent can raise special concerns for confidentiality. Furthermore, when information regarding a person's health has serious implications for the health of others, a dilemma may exist as to whether or not the health professional should break the obligation of confidentiality in order to prevent harm to others.

Competent patients have the right of access to information in their medical records, to have the data interpreted for them, and to object to the inclusion of specific information. Patients also have the right to correct inaccurate factual information held in their records. If patients want information deleted that could significantly affect subsequent care, physicians should inform them about the possible deleterious impacts of excluding the information, and make a note in their own records of informing the patients.

Advances in information technology offer both the promise of more accessible patient information for the patient’s best interest, but also greater risks of breaching the privacy and confidentiality of the individual. In addition, the demands for health information by medical insurance companies, legal bodies or other agencies may provide further challenges to the maintenance of confidentiality.

In combination with the more traditional principles of confidentiality or privacy, data protection principles add an additional level of security to private information. That is, when public agencies have legitimate access to personal data, they remain bound by duties of confidentiality. The means of storage of data, for instance in files or by electronic means, may be under the ownership of medical personnel or, for instance, clinical or hospital facilities, but the information remains under the control of the identified patient. Medical personnel and facilities are trustees of the information, bound by ethical duties of conscientious management for patients.
Recommendations

1. Patients have the right to ultimate control over the confidentiality of their data.

2. Physicians and health facilities should ensure that data stored about patients is accurate, complete and not excessive to the purpose of storage.

3. Competent patients have the right of access to information in their medical records, to have the data interpreted for them, and to object to the inclusion of specific information.

4. Every physician is obligated to respect and guard the individual patient's rights to privacy and confidentiality of their health information in all settings, including informal settings (e.g. hallway conversations, and in elevators, social settings, publications and lectures).

5. Security of electronic medical information, particularly when transmitting between institutions or to patients with electronic mail systems, requires strict adherence to security protocols, and the principles of data protection. The physician additionally should advocate for continual improvement of security of electronic records systems.

6. Not every member of a health care team is entitled to all patient information; but once information is received, every member has the same obligation of confidentiality.

7. When the health of a patient has serious and harmful implications for the health of others, the physician has an obligation to consult the individual patient and obtain permission to make the information appropriately available. In the case of direct, immediate, identifiable and life-threatening harm to a specific individual, the physician has an obligation to report the risk appropriately.

8. Parents normally have the right to be provided with information on the health of their dependent minor children and to engage in decision-making. However, the developing growth of the child’s capacity for decision making in health care is a continuous process and in some circumstances, where the minor is capable of
understanding the medical issues, the physician may be justified in withholding information from the family. This is also true when revealing information may directly lead to serious harm to the child.

9. No information regarding a patient should be divulged to an insurance company or to its medical representatives, or other agencies, without the express and informed consent of the individual patient.

10. Extra effort to ensure confidentiality of health records is required if breaching that confidentiality may prejudice an individual woman's safety or access to health care. This may require the maintenance of separate records or coding for sensitive areas, assurance of private and individual conversations with health providers, and clear procedures for notification of results of testing that are agreed on with the individual woman. Separate records or coding may compromise the overall healthcare of that individual, and this possibility must be discussed with the patient.

11. Health care information should be available for medical research and health care system improvement, provided it is securely anonymised.

12. Many circumstances surrounding an otherwise confidential medical encounter can endanger confidentiality. The title of a clinic, the letter head on a patient letter, the colour of contraceptive pills, the choices that an individual makes after consultation and other actions can all identify medical information that should be confidential. Attention to any secondary cues that surround the medical encounter that may compromise confidentiality is a critical part of ensuring patients’ confidentiality in health care.

13. Even if a physician does not have a patient/physician relationship, any medical information the physician receives regarding a patient must still be held in strict confidence.

_Luxor, November 2005_

**FEMALE GENITAL CUTTING**

1. Female Genital Cutting (FGC), sometimes referred to as female
genital mutilation or female circumcision, is a worldwide problem. It is practiced in all continents of the world. It is estimated that between 100 million and 140 million girls and women worldwide have been subjected to some form of female genital cutting. In spite of all efforts to abandon FGC, it is estimated that every year up to 3 million girls still undergo FGC in Sub-Saharan Africa, Egypt and Sudan.

2. Even though FGC is increasingly illegal throughout the world, this has not reduced the number of girls affected every year. Governments have no way of monitoring the spread and practice of FGC.

3. FGC is invasive physically and emotionally damaging. It is associated with immediate complications that may endanger the life of the girl, and with long term complications that may seriously affect her reproductive, sexual and mental health.

4. There is no established historical evidence to indicate in which continent FGC was first practiced, nor which type of procedure was first performed. It was practiced by Phoenicians, Hittites, Ethiopians as well as the Egyptians.

5. The cultural factors that support the continuing practice of FGC are several and include cultural identity, gender identity, belief that this controls women’s sexual and reproductive function, beliefs about cleanliness and hygiene, and belief that this promotes virginity and chastity and enhancement of male sexual pleasure.

6. The assertion that religion requires this procedure is refuted by many religious leaders as most faiths, including Islam, forbid physical violation of the human body, and the sacrifice of individual health and welfare to promote merely cultural beliefs of no benefit to communal well being.

Ethical Considerations

1. As affirmed in the FIGO resolution of 1994 in Montreal, FGC is unethical and also violates human rights principles.

2. Autonomy assumes the right of individuals to make decisions on their own behalf. FGC raises conflicts between choices parents make as surrogate decision makers for their children, their dependent children
and health professionals. At issue is victimization of vulnerable girls, in most cases between 4 and 10 years of age, for their parents’ beliefs, which requires that they receive special protections.

3. FGC violates the human rights to the highest attainable standard of health, and to bodily integrity in the absence of any medical benefit.

4. Medicalization of FGC, even if it may reduce the immediate health hazards of the procedure, underestimates its overall physical and psychological complications, and still offends ethical principles and human rights, particularly the rights of the child. It creates tacit approval, which only propels this cultural behaviour, rather than tacit disapproval and discouragement to change the behaviour.

5. FGC is an extreme example of discrimination based on sex as a way to control women’s sexuality; FGC denies girls and women the full enjoyment of their personal physical and psychological integrity, rights, and liberties.

6. FGC is an irreparable, irreversible abuse of the female child. It violates girls’ right to protection, contrary to the ethical principles of beneficence, justice, and non-maleficence.

Recommendations

1. Children should have the opportunity to develop physically in a healthy way, receive adequate medical attention, and be protected from all forms of violence, injury, abuse or mutilation. These rights should not be sacrificed for harmful cultural interpretation. This raises an obligation for health professionals and policy makers to promote public realization that it is possible to give up harmful practices without giving up meaningful aspects of their culture.

2. Education of the public, members of the health professions and the practitioners of traditional health care, community leaders, educators, social scientists, human rights activists and others who implement these policies, to trigger awareness of the extent of the problem and the dangers of FGC, is the best way to eradicate this practice.

3. Partnerships with religious leaders to ensure that misconceptions about religion and FGC are corrected, and to demonstrate the
absence of any religious requirement or support for the practice are important in achieving this change.

4. Eradication of FGC requires cooperation at the national and the international levels.

5. UN agencies, (including UNICEF, UNFPA, WHO), FIGO and other agencies active in this area have already taken steps towards abolishing this practice. Member societies of FIGO should join FIGO and international bodies in issuing firm guidelines for their members not to participate in this practice.

6. Women of all ages who have been subjected to FGC should be treated at all stages, including pregnancy and childbirth, with sympathy, respect, and medical evidence-based care. Depending on local laws, properly informed women who have been infibulated and who, following childbirth, independently request resuturing should not be denied treatment. However, practitioners should explain the benefits of unsuturing, advising women not to be exposed to resuturing. It should also be emphasized that all FGC procedures are professionally condemned.

7. Medicalization of FGC should be condemned at all national and international levels. It is the duty of professional bodies and organizations to advise members and all health workers not to undertake FGC, and to hold them accountable for this unethical practice.

London, March 2006

ETHICAL GUIDELINES ON CONSCIENTIOUS OBJECTION

Background

1. The primary commitment of obstetrician-gynecologists (“practitioners”) is to serve women’s reproductive health and wellbeing. Practitioners who find themselves unable to deliver medically indicated care to their patients for reasons of their personal conscience still bear ethical responsibilities to them. When practitioners feel obliged to place their personal conscientious
interests before their patients' interests, they have a conflict of interest. Not all conflicts can be avoided, but when they cannot, they can be resolved by due disclosure; that is, practitioners must inform potential patients of the treatments in which they object to participate on grounds of their personal conscience.

2. Practitioners have duties to inform their patients of all medically indicated options for their care, including options in which the practitioners decline to participate. When patients select such an option, practitioners are governed by the FIGO Ethical Framework for Gynecologic and Obstetric Care (2007), paragraph 7 of which provides that:

3. “If a physician is either unable or unwilling to provide a desired medical service for non-medical reasons, he or she should make every effort to achieve appropriate referral.”

4. Practitioners have the rights both to undertake and to object to undertake medical procedures according to their personal conscience. As medically trained and licensed practitioners, they are bound to apply the profession’s understanding of medical and reproductive science, and not to superimpose different characterizations of procedures based on their personal beliefs.

5. When in an emergency, patients’ lives, or their physical or mental health, can be preserved only by procedures in which their practitioners usually object to participate, and practitioners cannot refer such patients to non-objecting practitioners in a timely way, the practitioners must give priority to their patients' lives, health and well-being by performing or participating in the indicated procedures.

Guidelines

1. The primary conscientious duty of obstetrician-gynecologists (hereafter “practitioners”) 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 treating a patient is secondary to this primary duty.

2. Provision of benefit and prevention of harm require that practitioners
provide such patients with timely access to medical services, including giving information about the medically indicated options of procedures for their care and of any such procedures in which their practitioners object to participate on grounds of conscience.

3. Practitioners have a professional duty to abide by scientifically and professionally determined definitions of reproductive health services, and to exercise care and integrity not to misrepresent or mischaracterize them on the basis of personal beliefs.

4. Practitioners have a right to respect for their conscientious convictions in regard to both undertaking and not undertaking the delivery of lawful procedures, and not to suffer discrimination on the basis of their convictions.

5. Practitioners’ right to respect for their choices in the medical procedures in which they participate requires that they respect patients’ choices within the medically indicated options for their care.

6. 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.

7. Practitioners must provide timely care to their patients when referral to other practitioners is not possible and delay would jeopardise patients’ health and well-being, such as by patients experiencing unwanted pregnancy (see the FIGO Definition of Pregnancy, that pregnancy “commences with the implantation of the conceptus in a woman”).

8. In emergency situations, to preserve life or physical or mental health, practitioners must provide the medically indicated care of their patients’ choice regardless of the practitioners' personal objections.

Luxor, November 2005
PROFESSIONAL OBLIGATIONS TO FELLOW OBSTETRICIAN/GYNECOLOGISTS

Obstetrician/Gynecologists have responsibility for a broad scope of care for women of all ages. In the course of delivering competent, responsible and evidence-based care within appropriate legal parameters, individuals in member societies have faced intimidation and abrogation of their civil and human rights. It is the professional obligation of every member society and its individual members to advocate for the rights and security of each obstetrician/gynecologist to practice their profession within the law and with protection from interference or intimidation from any source – governmental or nongovernmental.

London, March 2006

HARMFUL STEREOTYPING OF WOMEN IN HEALTH CARE

Background

1. The United Nations’ Convention on the Elimination of All Forms of Discrimination against Women, in Article 5(a), requires measures for “the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes or on stereotyped roles for men and women.” It may also be noted that a similar provision is included, for instance, in the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa, Article 2(2).

2. A stereotype is a generalised view or preconception of attributes possessed by a population group with which an individual is identified. It presumes how that individual, because of ascribed membership of that group, feels, is able to act, and wants to act, without regard to that individual's personal disposition, capacities, and qualities. A stereotype is applied impersonally by those who are ignorant of, or indifferent to, the actual characteristics, wishes, likes, and dislikes of the individuals they regard only through stereotypes.

3. Stereotyping of others is a common phenomenon of human perception. Stereotypes provide an initial sense of people we do not
know, and serve to place them within a framework familiar to ourselves. The harm of stereotyping occurs when healthcare providers simply apply stereotypes without acquiring knowledge of their patients’ or colleagues’ true characteristics, wishes, and intentions, or without showing respect for their particular individuality.

4. Stereotypical thinking about women, their roles in society and in their families, their capacities, and their preferences has permeated health care in general and reproductive health care in particular. Stereotypes have included beliefs such as the following: women desire more than anything else to bear children and will willingly sacrifice any other interests of their own to motherhood; they will provide care to their family members; they are vulnerable and incapable of reliable or consistent decision-making; they will be supported by men folk ("breadwinners") in their families; and they will be subordinate to men such as fathers, husbands, brothers, co-employees, and doctors. Comparably demeaning stereotypes are that unmarried women seeking contraception are promiscuous and that women willing to serve as surrogate mothers have mercenary motives.

5. Laws may reinforce the stereotypes of women as dependents and subordinates. Where males legally control and/or are primary contributors to family resources, and make payments for health services and/or insurance, male family members may have to be asked to approve women’s care. This reduces women’s rights to independent decision making. Such males’ legal authorization has to be adequately informed of the dependent women's medical circumstances, so that the women's confidentiality may be compromised, further reducing their rights to self-determination.

6. In hospitals and comparable healthcare facilities, doctors are usually senior employees or act under independent contracts for their services. In women-dominated professions such as nursing, women are often legally engaged as “servants,” under master-servant contracts. Although nursing is increasingly recognised as independent of the control of doctors, the profession still struggles in many geographic and practice areas to be acknowledged as independent of doctors’ control of performance standards.
7. Some of the harms that have resulted from stereotypical attitudes include pregnant women being denied treatments and disclosure of available treatments that are medically indicated for care of pregnancy-unrelated conditions, such as cardiovascular disease and cancers, because such treatments may compromise fetal survival or wellbeing. The stereotypical presumption is that the general inclination of women is to be self-sacrificing mothers-to-be who would place fetal interests above their own. This denies pregnant women the right to balance the competing responsibilities in their individual lives according to their personal preferences and assessments. The stereotype of women's vulnerability and emotionalism may lead a healthcare professional to withhold information necessary for a woman's informed consent because it may be distressing or could provoke anxiety.

8. A stereotype is being actively promoted in the contested area of abortion, where laws are becoming progressively liberalised, rejecting claims that fetal interests are inherently superior to those of pregnant women's. The argument is therefore made against abortion that termination of their pregnancies is harmful to the women themselves because they will come to regret such decisions and suffer remorse. This argument is based on the false stereotype that women make fickle, changeable, impulsive decisions governed by emotions of the moment, and require the guidance of steadfast, more discerning, usually male protectors of their interests.

9. Medically assisted reproduction can raise the same stereotype of women as poor guardians of their own interests: for example, that women are too old for childbearing or too careless in their willingness to accept the risks of hormonal ovarian stimulation for in vitro fertilization or for ovum donation. Women may be similarly considered incapable of deciding whether to undertake natural or assisted conception when they are HIV-positive.

10. A considerable body of literature records verbal and analogous abuse or demeaning of healthcare workers, especially female nurses, by senior medical staff. A particular concern is sexual harassment of junior staff. This reflects the history of sexual abuse of female patients by male healthcare providers, at every level of authority. Beyond
abuse are stereotypical assumptions that female doctors will specialise in women's health concerns, such as reproductive health, pediatrics, and psychosocial work, and will provide empathetic emotional support for patients, of both sexes, not expected of male doctors.

Recommendations

1. Healthcare providers should offer or recommend care only when they know their patients as the individuals they are, not simply as “types of patients” or possessors of symptoms. Patients’ presenting conditions and superficial appearances must not be taken to define them as members of a general category of persons.

2. Healthcare providers dealing with women patients should be aware of, and resist, their own and others’ tendencies to consider women through stereotypes, such as women being emotional, vulnerable, seeking their principal personal or social fulfillment in motherhood, or lacking sound moral judgment. In particular, providers should not bar women's access to health services by negative female characterizations: for instance, that women are predestined by nature only to domestic or subservient roles.

3. Similarly, as colleagues, teachers, principal investigators, members of appointment or promotion committees, and in their other nonclinical functions, healthcare providers should ensure that negative stereotyping of women is avoided.

4. Healthcare providers must be vigilant and self-critical in order not to treat female colleagues, especially their more junior female colleagues, in ways that demean, humiliate, or otherwise indicate their inferior worth as individuals. Differences in capacity to perform healthcare services should be recognised non-judgmentally, with care not to endorse “the idea of the inferiority or the superiority of either of the sexes or...stereotyped roles for men and women.”

5. Healthcare providers must be vigilant to recognise and redress their own tendencies to approach women patients, prospective patients, colleagues, and others through restrictive or negative stereotypes. They should promote women’s dignity and rights to pursue self-fulfillment equally with that of men.
6. Healthcare providers must be equally proactive to identify and redress any tendencies of their colleagues, their healthcare institutions, and their professional organizations to approach women through similarly demeaning stereotypes, and teach by instruction and example the promotion of women's equal dignity and rights.

Goa, March 2011

ADOLESCENT AND YOUTH REPRODUCTIVE HEALTH CARE AND CONFIDENTIALITY

Background

1. Improving the sexual and reproductive health of young people reduces the likelihood of teenage unmarried pregnancy and its heavy immediate and long-term social and economic costs. Delayed, noncompelled marriage and well-timed parenthood promote greater social and economic opportunities from which individuals, families including their young children, and societies all benefit. Prevention of sexually transmitted infections (STIs), including HIV/AIDS, reduces social stigma, and helps young people and the families they will later create to remain healthy.

2. Health professionals, especially gynecologists, should give emphasis to improving young persons’ access to education and sexual and reproductive health services. Health professionals should take care, and encourage those with whom they collaborate to take care, to respect, protect, and promote young persons’ rights to sexual and reproductive health services.

3. Rights to sexual and reproductive health include rights to confidentiality of health services requested and provided. Young persons’ fears that their confidentiality will be violated may deter them from seeking or accepting education and services for protection and promotion of their sexual and reproductive health, including protection against STIs and suffering or causing unwanted pregnancy.

4. The UN Convention on the Rights of the Child, endorsed by all but two of the world’s countries, recognises that rights of a young
person’s parents or other adult guardian shall be observed “in a manner consistent with the evolving capacities” of the young person. Many legal systems incorporate this principle by recognizing the independent decision-making capacity of “mature minors.” Further, the Convention provides that “In all actions concerning children [up to 18 years unless made independent earlier by law] ...the best interests of the child shall be a primary consideration.”

5. Assessments of young persons’ capacity may involve consultation with other medical and related professionals, under regular conditions of professional confidentiality. Determination of young persons’ best interests shall be informed by their own views and preferences, which the Convention requires shall be “given due weight in accordance with the [young persons’] age and maturity.”

6. Pregnancy is a leading cause of death worldwide among women aged 15 to 19, due to childbirth complications and unsafe abortion. Sexual activity also results in young persons’ morbidity from pregnancy and STIs. An estimated almost 12 million youths live with HIV/AIDS, of whom 62% are women.

7. Young people require unimpaired access to the full range of sexual and reproductive health services, including education, counselling, and means to ask questions without embarrassment, guilt or recrimination. Their human rights to health services, particularly preventive care, include delivery of care in secure conditions that ensure their confidentiality to a maximum extent, consistently with their evolving capacity to make decisions in their own lives.

Recommendations

1. Healthcare providers should recognise that adolescents and youths can possess capacity to make substantial life choices for themselves. Chronological age should not determine young persons’ rights to make sexual and reproductive health choices for themselves. Rights should be determined by their individual capacity to understand effects and implications of their choices.

2. Adolescents and youths found capable of making treatment and
related decisions for themselves should be afforded the medical professional confidentiality that adult patients enjoy, and be made.

3. Aware that such confidentiality will be properly protected.

4. National societies and gynecologists/obstetricians should urge reform of laws and policies that restrict young persons’ access to reproductive health care, and work with governments, politicians and, for instance, non-governmental organizations to advance young persons’ sexual and reproductive health education and rights of access to confidential services.

5. Young patients should be encouraged to involve their parents, adult guardians and/or friends in their care, and be offered counselling on their refusal, particularly when sexual abuse or exploitation may explain refusal. Young patients’ explanations of their circumstances should be taken seriously and appropriate assistance offered.

6. Care should be provided non-judgmentally, but practitioners and/or counselors may advise of the disadvantages of premature sexual relations, including risks of STIs such as HIV/AIDS. Provision of care should be sensitive to young persons’ capacity to consent, and take account of their reasonably foreseeable future if care is not provided.

7. Care providers should ensure that access to their facilities, and their facilities’ waiting and counselling areas and treatment rooms, preserve young persons’ confidentiality.

8. Young patients should be offered comprehensible literature to keep that explains options of care, or a telephone help line through which to obtain sexual and reproductive health advice anonymously. Providers should remember that costs and logistics of services may determine whether young persons will have access to advice and services.

Paris, October 2008
Introduction and background

1. Cervical cancer is the most common cause of death from cancer for women in developing countries and is increased within developed countries for women who have decreased access to health care.

2. Women have a right to the highest attainable standard of physical and mental health and to have their health rights addressed by their governments.

3. HPV subtypes 16 and 18 are the proximate cause of 70% of cervical cancer worldwide with regional patterns that include multiple other oncogenic subtypes.

4. HPV is a sexually communicable disease for which the burden of death and disability falls disproportionately on women.

5. Cervical cancer is now a virtually preventable disease through a combination of early vaccination and screening strategies to identify and treat pre-invasive disease.

6. In order to be effective, the present vaccines to HPV 16 and 18 must be given at an age before likely viral exposure.

7. Delay in vaccination roll out will result in additional generations being at risk for cervical cancer.

Recommendations

1. Education of both health professionals and communities about prevention of cervical cancer through both vaccination and screening strategies is an obligation of health professionals, in particular Obstetrician/Gynecologists.

2. The development and maintenance of screening strategies must be addressed for women regardless of vaccination strategy, due to the ongoing risk for unvaccinated women, women who were exposed prior to vaccination, or those with an uncovered oncogenic HPV subtype.
3. Obstetrician/Gynecologists should advocate for youth-friendly approaches to vaccination and screening that include primary care, pediatric and other health professionals and address the unique issues of privacy and confidentiality for this age.

4. Development of community/national/NGO/WHO partnerships is needed to create affordability for vaccination and screening programmes to prevent cervical cancer.

5. Obstetrician/Gynecologists have an obligation to advocate for vaccination and screening and to assist in the creation of coalitions to address prevention of cervical cancer.

Lyon, June 2007

JUST INCLUSION OF WOMEN OF REPRODUCTIVE AGE IN RESEARCH

Background

Women of reproductive age have been directly excluded from research due to the concern of a potential of pregnancy in this age; indirectly by creating high barriers to inclusion with serial pregnancy testing and contraceptive requirements; and by cultural and legal barriers that preclude women of reproductive age from making decisions about their care including participating in clinical trials. The consequences of this are significant as they result in drugs being used in populations they are not tested in, increasing the rate of drug reaction or failure as well as preventing access to new drugs that might be lifesaving. The arguments of fetal protection that exclude women of reproductive age question a woman’s ability to make reasoned choices about fertility while on a clinical trial, reducing her rights to make choices about health care, reproduction, and participation in clinical trials.

Guidelines

1. Participation in clinical trials for women of reproductive age requires the capability of women to make their own choices, free of coercion, about healthcare as well as access to family planning.
2. Women of reproductive age are capable of making decisions about risks of potential teratogenicity as part of the decision-making around whether to participate in a clinical trial, and should be given their choice. Even in the setting of no access to contraception or abortion, a woman’s right to consider the risks of a clinical trial, in terms of teratogenicity and her own reproductive capacity, should belong with the woman.

3. Requirements to “prove” infertility with multiple pregnancy tests, or proof through pathologic confirmation of hysterectomy or oophorectomy, can raise psychological and practical barriers that discourage and can psychologically harm potential research subjects.

4. Consent to participate must always be the autonomous, informed choice of the women of reproductive age.

5. A key benefit of inclusion is identifying potentially harmful side effects in a carefully controlled trial setting rather than post marketing and use where more women stand to be harmed before untoward side effects are identified. Women have an equal right to the benefits (and harms) of research and to the knowledge gained that will inform better dosing and drug information after market entry.

Paris, October 2008

DISCLOSING ADVERSE OUTCOMES IN MEDICAL CARE

Adverse outcomes and errors happen in medicine. Some are truly unpreventable. Some are system errors that should be actively explored to prevent future harm and increase patient safety. Physicians and health care professionals have an ethical obligation to disclose to patients adverse outcomes and others affected (healthcare team, health systems) based on truth telling as well as the obligation to ensure patient autonomy. The process of disclosure requires skills in empathetic communication that can be learned but are not presently a part of the curricula of medical training. Furthermore, the culture of blame created by the fault based litigation in many venues works against this approach to errors. Regardless, physicians must lead the initiatives to increase systems analysis, compassionate disclosure of adverse outcomes to increase the level of patient safety and to ensure patient trust in health professionals and medical institutions.
1. The ethical imperative to tell the truth to patients is based on the importance of trust in the physician patient relationship and the right of patients to make choices (autonomy) for their own health care. Without an understanding of their health care circumstances, they cannot formulate the best decisions for their own care within their own framework of values and needs.

2. Adverse events affecting patient care, such as where there is an unexpected occurrence involving physical or psychological injury, loss of body part, disability or loss of bodily function need to be discussed with patients and/or their families.

3. The goal is to tell patients and/or families as appropriate about an untoward outcome in a timely fashion, to ensure continuing communication as systematic analysis of the event reveals gaps in the system. Continued communication about what the physician and/or institution is doing to ensure that this does not occur again is also important.

4. The explanations should include the nature of the event as well as the short and long term health consequences.

5. The individual communicating with the patient is preferably the physician or provider themselves. However, if there is no training or support for communication of adverse events, an individual with those skills might be a better choice to ensure that the truth is told with empathy and counseling is provided.

6. It is important to tell patients and/or families that the physician or health care team regrets that this has happened to them, and is determined to see what can be done to alleviate their problems from the event and to figure out how to ensure that it does not happen to someone else.

7. Concerns about expressing regret about an outcome as increasing legal liability should not inhibit the achievement of the ethical requirement to tell the truth and to increase patient safety.

8. Physicians and other healthcare professionals also have obligations to report to existing safety systems at institutional or governmental levels. If none exist, advocacy for these systems and the accountability
of administrations of health systems to address safety and quality is important.

9. Increased training regarding communication with patients and/or families about adverse events as well as systems thinking should be part of medical education including continuing medical education.

London, March 2010

CROSS BORDER REPRODUCTIVE SERVICES

Background

1. Cross border reproductive services refer to individuals crossing national borders to obtain fertility treatment outside their home countries, and to individuals leaving their own countries to facilitate reproduction elsewhere, for instance as gamete donors or surrogate mothers.

2. The reasons for crossing borders vary. Common reasons are the pursuit of personal autonomy motivating avoidance of restrictive laws, such as when a country forbids a reproductive technique, or a particular population group is excluded from access. Other reasons include lack of services in the home country, long waiting lists, better quality of care or less expensive treatment in another country.

3. If health care professionals suggest treatment abroad, they have an obligation to ensure that, like for any other health care referral, they have general knowledge of the safety and quality of care at the site they suggest, for the purpose of facilitating patients’ choices. In some countries, it may be illegal to refer for treatment abroad that is deemed illegal in the home country.

4. Because of such constraints on care within countries outlined above, cross border care can overcome limits on patients’ autonomy. Health care providers have the responsibility to discuss with their patients what is medically appropriate for the patients to consider, even if that option may not be available locally, to inform patients’ decisions and ensure respect for their autonomy.
5. Potential harmful outcomes of cross border reproductive care include medical and legal complications, and negative impacts on health care resources in host and/or patients’ own countries. There may not be practical legal recourse for patients who suffer harm and complications from procedures performed abroad. The number of multiple pregnancies may be higher, creating risks for both prospective mothers and their children. Patients may return home without adequate information about their prior treatment, adding substantially to the risks and costs of care. Costs and sequelae of complications fall primarily on the patients’ home countries’ health care systems. Further, cross border care to produce a child of a specific sex, forbidden in the home country, may create or aggravate harmful social effects in some home countries.

6. Macroethical consequences of cross border services may be diversion of scarce physician and related talents towards reproductive care for visiting patients, and away from care of domestic patients, unless visiting patients’ fees cross-subsidize treatment for less affluent domestic patients. However, economic incentives may induce patients or egg donors to risk suffering health complications, the costs of which fall on their home countries. This may also have ethical ramifications relating to the unacceptable commodification of women as egg donors, denying them recognition and value as unique individuals.

Recommendations

1. Professionals and professional societies should support patients’ access locally to evidence-based reproductive care in a fair and equitable manner, without discrimination.

2. Professionals and professional societies in every country should each create a Code of Practice or system of certification to ensure that patients and other participants in reproductive services receive safe and effective care wherever they go.

3. Professionals and professional societies should ensure compliance with ethical standards in the offer of medically assisted reproductive services, including provisions that address the welfare of future
children, and safety and quality of care for both patients and participants.

4. Provision of appropriate counseling should be encouraged internationally for patients and participants, both at the home and at referral sites.

5. FIGO and national societies should encourage information campaigns by local professional organizations to educate the general public about potential harms of cross border reproductive care.

6. All professional parties, including other referring agents, and physicians and related team members caring for patients in receiving countries, should provide their patients and participants with full medical information about their care to ensure their receiving due care at home.

7. Cross border reproductive care involving egg donation or surrogacy services has the potential to exploit and commodify women, enticing them to risk their health, and that is unacceptable. Any related practice should be in compliance with the Committee’s ethics recommendations, such as on Donation of Genetic Material for Human Reproduction (June 2007) and on Surrogacy (June 2007).

8. Cross border services including sex selection are unacceptable except in compliance with the Committee’s recommendations on the ethics of Sex Selection for Non-Medical Purposes (March 2005).

9. Cross border referrals to reproductive care, particularly in low resource countries, should avoid shifting resources in such countries to the care of visiting patients, to the detrimental compromise of the services available to meet the treatment needs of the resident population.

London, March 2010

**BRAIN DRAIN OF HEALTHCARE WORKERS**

**Background**

1. The worldwide shortage of healthcare workers, coupled with a
disproportionate concentration of health workers in high-income nations and urban areas and the “brain drain” of the health workforce from low-income countries, stands in the way of reducing child and maternal mortality, increasing vaccine coverage, and battling epidemics such as HIV/AIDS in low-income countries.

2. Africa bears 24% of the global burden of disease, but has only 3% of the health workforce. High-income countries have only one-third of the world’s population, but they contain three-fourths of world’s physicians and 89% of the world’s migrating physicians. Approximately 180 000 (25%) of American's physicians are trained abroad, with 64.4% of them in low- and lower/middle-income nations.

3. Shortage and maldistribution of healthcare workers – aggravated by the brain drain of the health workforce from Africa, Asia, and Pacific countries to high-income countries – contributes to maternal and newborn deaths and morbidity at vastly different rates in high- and low-income countries.

4. About 35% of pregnant women in low-income countries have no access to or contact with health personnel before delivery. Only 57% give birth with a skilled attendant present. Rural and poor women often have no access to maternal health services or cannot afford it. Thirty-six countries in Sub-Saharan Africa have severe shortages of health workers.

5. Annually, more than half a million women die in pregnancy or childbirth. Some 9.2 million children die before their fifth birthday – nearly 40% of these in the first month of life. More than 99% of all maternal deaths occur in low-income countries, with some 84% concentrated in Sub-Saharan Africa and South Asia, where the brain drain hits most.

6. Evidence shows that we could save at least 7 million of these lives each year with proven, cost-effective interventions, which requires the availability, training, and retaining of adequate numbers of health workers. Brain drain creates a bottleneck to improving maternal, neonatal, and child health (MNCH) and fighting HIV/AIDS, and translates into loss of potential employers, teachers, and role models.
7. At least 2.3 trained healthcare providers are needed per 1000 people to reach 80% of the population with skilled attendance at birth and child immunization. It will take an additional 2.4 million physicians, nurses, and midwives to meet the needs, along with an additional 1.9 million pharmacists, health aides, technicians, and other auxiliary personnel. However, most of the demand is concentrated in industrialized countries because of a largely growing, aging population and increasing demand for high-tech care.

8. High-income nations spend US $500 million each year to educate health workers who leave their home countries to work in North America, Western Europe, and South Asia.

Guidelines

1. A code of practice on the international recruitment of health personnel should be developed. WHO advocated a comprehensive, four-pillar approach including: improvement of data on health workers' migration, development of innovative policy responses, evaluation of the effectiveness of international interventions, and international advocacy for workforce issues.

2. Brain drain of the health workforce from low- to high-income countries should be regulated. It deprives source countries of the scarcest human resources, undermines health services, and markedly widens the 90/10 gap between high- and low-income countries.

3. Temporary return of qualified health professionals and their virtual participation through conferences, telecommunications, and internet, should be encouraged as it contributes to improvement of health care in the country of origin.

4. Recipient high-income countries of health professionals should develop a mechanism of assistance and transfer of healthcare technology to low-income countries from which they receive a large number of health professionals.

5. Recipient countries should ensure availability of suitable jobs in their health system before issuing immigrant visas to health professionals from other countries.
6. High-income countries should invest in medical education and training of health professionals to overcome the insufficient overall investment that exists and is compensated for by facilitating brain drain from low-income countries.

7. In some countries where the underproduction of healthcare workers is a major problem, task-shifting and the assembly of new cadres of workers should be encouraged. Nurses and pharmacy assistants and other paramedics may fill gaps in care.

8. In low-income countries, particularly Sub-Saharan Africa, Southeast Asia, and Latin America, locally relevant medical training and research should be implemented to address endemic problems with significant mortality such as malaria, HIV, sexually transmitted diseases, multi-drug resistant tuberculosis, bilharziasis, malnutrition, and childhood diarrhea. It should lay special emphasis on clinical examination skills and the use of evidence-based locally-adapted guidelines and simplified diagnostic and therapeutic procedures.

9. Community oriented research and postgraduate training programs in obstetrics and gynecology should be encouraged in low income countries to increase retention and encourage return to country of origin.

10. Countries that produce excess numbers of health workforce personnel should strengthen links with their expatriates and provide assistance, such as departure preparation, return, arrangement for suitable jobs, dual citizenship, encouragement of foreign direct investment, ensuring that migrants become familiarized with the culture of the other country before leaving their own and learning the language to facilitate their integration in the society. In return, arrangements should be made for migrants to contribute to education, health care, and developments in their countries of origin by taxation, which they would have paid had they stayed in their home country.

11. International cooperation and political commitments are required to overcome instability, armed conflicts, brutal regimes, and improvement of remuneration and working conditions of health professionals, particularly in low-income countries. This will
encourage immigrant health professionals to return to their countries of origin and discourage others from leaving their countries.

Paris, October 2008

ISUES IN GENETICS AND PRE-EMBRYO RESEARCH

HUMAN CLONING

Background

1. In 1997 the birth of the first cloned mammal by Somatic Cell Nuclear Transfer (SCNT), the sheep Dolly, demonstrated the feasibility of asexual reproduction of mammals. In addition, success in other mammals has also been reported, raising the possibility that reproductive cloning may lead to the birth of humans.

2. This technique has a low success rate, a high miscarriage rate, and complications like the large offspring syndrome and immune system failure. Thus, SCNT for reproduction is deemed unsafe by virtually all scientists. This in itself constitutes an overwhelming objection to its use for human reproduction at the present time.

3. SCNT research is necessary as the technique may prevent rejection of the donated cells and be a unique tool for understanding of genetic disorders. Most scientists agree that research should continue with SCNT in humans at least for the purpose of therapeutic cloning.

Recommendations

1. Public education about the differences between reproductive and therapeutic (sometimes called “research”) cloning is important.

2. Cloning to produce a human individual by SCNT is unacceptable on grounds of safety. Such research in animals may be ethically justified because it has the potential of human benefit.
3. Research on human embryo stem cells, produced by SCNT, to produce various cell lines for therapeutic purposes, is encouraged to alleviate human suffering, subject to tight ethical guidelines.

*Luxor, November 2005*

**PATENTING HUMAN GENES**

**Background**

1. The human genome has been fully sequenced, and some patent offices have granted patents on many human genes. Patenting systems were put in place by governments to encourage innovation. Patenting provides an inventor with monopoly rights for a period of time in exchange for revealing to the world at large the details of the invention, so it can become part of the public storehouse of knowledge.

2. Many beneficial products and processes are now available, including effective therapeutic and preventive agents for serious diseases, because of the investment in research that is encouraged by patenting. However, patent law was developed to deal with inert matter, and we need to assess whether the same approach is appropriate to human genes.

3. Patenting decisions are currently being made in patent offices, which are not structured in a way that takes into account the broader social, health, economic and ethical implications of patenting human genes.

4. The human genome is seen by many as belonging to everyone, and allowing privatisation of certain gene sequences by patenting is seen as a private take-over of our common heritage. Adding weight to this view is that much of the ground-work of research and knowledge about DNA has been funded by tax-supported research bodies and by medical charities.

5. Permitting human genes or fragments of the human genome to be patented has distributional economic effects both within and between countries. Money and power will accrue to the holders of these patents, which are likely to be large multinational companies.
6. There is also a danger that the need for financial return on the large investments made by such companies will lead to aggressive marketing and to premature use, or to over-use, of gene probes or products. Even though private funding from industry provides a large proportion of funding for research and development in this field, allowing appropriation of human genes by private commercial interests may not result in net benefits for the common good.

Recommendations

1. Governments and the international community have a responsibility to address this area if the public interest is to be protected.

2. In the meantime, patent offices should exercise great caution and proceed with prudence in evaluating any applications. This evaluation should include consideration of the broader social and international implications.

3. The way that we deal with patenting and human genes has consequences for humankind. It is a global problem, not able to be dealt with by any nation alone.

4. Therefore, we call for the UN system in particular, as well as publicly elected bodies, to study and debate the issues so they can be decided in a democratic fashion with the long-term public good in mind.

Basle, 1997

EMBRYO RESEARCH

Background

1. Studies on the use of animal embryonic stem cells have been published since the early 1980s. Cell differentiation research and therapeutic use in order to regenerate tissues in a wide range of serious, but common, diseases have been reported.

2. Stem cells retain the ability to self-renew and to differentiate into one or several cell types. Stem cells may be derived from the embryo, cord blood, the fetus or the adult. In the human, these cells may be
obtained from supernumerary embryos (at the blastocyst stage) in IVF cycles, embryos created de novo from donated gametes, or possibly embryos cloned by Somatic Cell Nuclear Transfer (SCNT).

3. Embryo research is necessary to further improve fertility treatment. Animal evidence holds promise to elucidate the usefulness of stem cell technology for combating many diseases as well as to improve fertility treatment. However, there are specific concerns about the use of human embryos in research that derive from the uncertain status of the pre-implantation human embryo in most societies.

4. An ethical dilemma concerns the necessity of creating embryos specifically for research. The creation of pre-implantation embryos specifically for the purpose of research, and research on such embryos, are appropriate only if the information cannot be obtained by research on existing supernumerary embryos.

5. It is essential that neither men nor women should be coerced or unduly induced into donating sperm, oocytes or embryos for research.

6. A major concern when embryos are created de novo is the source of the oocytes, for the purpose of SCNT. The procedure entails more risks for the female, who consequently needs careful protection by the provision of information about the implications of her gift. New techniques like In Vitro Maturation (IVM) offer alternative sources of oocytes. Immature oocytes may be obtained from ovarian tissue of fetuses, children and pre- and post-menarchal women. The ethical implications of each source are complex and controversial.

Recommendations

1. When gametes are collected, specific consent for the possibility of research on the creation or use of embryos must be sought.

2. In IVF programmes, recipients of resulting embryos may shall be asked for consent to the use of their supernumerary embryos for research.

3. Embryos should not be created for purposes of research unless there is a demonstrable need for the planned studies, which must be
submitted to ethics committee appraisal and peer review. Research into alternative treatments should also continue.

4. Women must be protected from coercion or undue inducement to donate oocytes, especially when they are vulnerable medically, psychologically or socio-economically.

5. Because oocytes are a scarce resource for infertile women and research, their allocation to one or the other requires ethical justification.

Luxor, November 2005

ETHICAL GUIDELINES ON THE SALE OF GAMETES AND EMBRYOS

1. The Committee reaffirmed the former statement made in 1993\(^1\) that the donation of genetic material should be altruistic and free from commercial exploitation. Reasonable compensation for legitimate expenses is appropriate.

2. The Committee noted that some centres offer IVF cycles, sterilisation or other medical treatment to women in exchange for donation of oocytes. This is considered to be payment, and therefore is unethical.

3. It should also be noted that when payment is involved, donors may be tempted to withhold personal information which, if known, would make him or her unsuitable as a donor.

4. The Committee considers that the management of donated gametes and embryos should be regulated by a governmental authority.

Ljubljana, 1996

ETHICAL GUIDELINES REGARDING ALTERING GENES IN HUMANS

1. Rapidly advancing scientific information about the human genome and a growing ability to manipulate DNA have raised many issues as

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to how this genetic knowledge should be applied to people. Since the 
application of scientific knowledge to human reproduction lies within 
the sphere of obstetrics and gynecology, it is important that 
practitioners in these fields be aware of the many important ethical 
implications raised by potential uses of genetics.

2. The term “gene therapy” has been used to refer to the alteration of 
human DNA for various purposes. This is misleading; it is essential to 
recognise that not all alterations are “therapy”. Only when the 
geometric alteration is made in order to alleviate suffering in an 
identified individual with a disease can it properly be termed “gene 
therapy”.

3. Alteration of human genes can be thought of in three categories, each 
of which has different ethical implications. These are geometric 
alteration of somatic cells to treat disease (gene therapy), germ line 
geometric alteration, and non therapeutic geometric alteration (geometric 
enhancement).

4. Genetic alteration of somatic cells to treat disease 
   (i) Since the altered geometric material is not inserted into the germ 
cells, the alteration is not passed on to future generations. 
Somatic geometric alteration raises many important issues, in the 
same way that research in humans on some other new experimental therapies does. For this reason, any research projects proposing to alter the DNA of somatic cells of human subjects for therapeutic purposes should receive prior review and approval by a properly constituted research ethics board under a governmental authority (as described below). Aspects to be 
evaluated in the review should include detailed data on safety 
and risks, on whether there is fully informed consent, and on 
measures to protect confidentiality.

   (ii) Such research projects altering DNA in somatic cells should be 
considered only for serious disorders which cause major 
debilitation or early death, and that cannot be treated 
successfully by other means.

   (iii) If the results of these gene therapy research projects are 
successful, future proposals may be made to use somatic cell geometric 
alteration in the fetus in utero. Such proposals should have
additional scrutiny to ensure that the autonomy of women is respected, and that an adversarial relationship between a woman and her fetus is not created.

5. Germ line genetic alteration

This involves changing the gametes of an individual so that the genetic change is passed on to subsequent generations. There are at present no techniques available to alter specific genes precisely, reliably and safely. When prospective parents have mutant genes it is possible to identify among their zygotes those that have not inherited the mutant allele(s). Such parents have the opportunity to have their normal zygotes implanted in the uterus. Given the current and immediately foreseeable state of knowledge, it is safer and more appropriate to transfer to the uterus zygotes that are unaffected by the disease gene, than to identify affected zygotes, try to alter their DNA and implant them. Therefore, at the present, research involving alteration of the DNA of human zygotes, or of an egg or sperm used to form a zygote that is to be implanted in the uterus, is not ethically acceptable and should not be permitted.

6. Non therapeutic genetic alteration (Genetic enhancement)

This involves the attempt to enhance or improve a person’s already healthy genetic makeup by inserting a gene for “improvement” (for example, height, intelligence, eye colour). Many questions have been raised about criteria for access to this kind of technology, and what the social consequences would be of allowing the market place to determine how such technology would be used. There is potential for profit in marketing such technologies: yet this is a field where individuals do not have the knowledge to protect their own interests. The risks involved, with no sufficient justification for undergoing these risks, mean that research in human subjects involving the alteration of DNA for enhancement purposes is not ethically acceptable and therefore should not be permitted.

7. In summary, it is clear that the application of genetic alteration to human beings raises the likelihood of harm and exploitation of individuals. Because of this, governments have a duty to put in place
legally based authorities to limit, oversee and ensure accountability for activities in this field.

Ljubljana, 1996

DONATION OF GENETIC MATERIAL FOR HUMAN REPRODUCTION

Background

1. The donation of genetic material whether sperm, oocytes or (pre-implantation) embryos, in order to create children raises a number of ethical as well as social, religious, and legal issues.

2. Genetic material donation has been mainly used to overcome infertility for which no other treatment exists, or if costs are less, whether infertility is male (with sperm donation), female (with oocyte donation), or affecting both parties in the couple (with embryo donation). These conditions may be genetic, congenital, or iatrogenic, for example after chemotherapy for cancer, which may result in testicular or ovarian failure. Gamete donation has also been used in grave genetic disorders in order not to transmit a grave disease to offspring, for single women or women in female couples wishing to have biological children, for the achievement of postmenopausal fertility in older women, or in the management of habitual spontaneous abortion.

3. Some countries forbid genetic material donation to single or same sex couple women. There is no evidence in published studies of a negative impact on the offspring. Legislative choices, rather than medical indications, have impacted prevailing policies.

4. In order to ensure safety for recipients and offspring of genetic material donation, many countries have, and all should have, regulations regarding the cryo-preservation (banking) of sperm, ova and embryos, the screening of donors, standards in the laboratory, the quality of the medical management, and respecting safety when collecting gametes and embryos. Finally, advance decisions by
legislation or contract concerning the disposal of genetic material and accurate record keeping are essential.

5. Screening of donors should provide means to ensure that donors of genetic material are healthy persons of normal reproductive age who are free from sexually transmitted diseases and known hereditary disorders. Thorough screening should follow national and internationally approved guidelines, and an abnormal test result should be made available to the donor, with counselling when necessary. Genetic material from a dead person should not be used unless a written statement by the donor when alive exists. When death is sudden or unexpected, genetic material cannot be obtained from the deceased. Further, non-members of the medical team involved in the management of a recipient should not be donors.

6. Although the term donation implies non-payment, some compensation is often offered. Donation of genetic material should be altruistic and free from commercial exploitation. Reasonable compensation for legitimate expenses of donation is common. If the monetary compensation markedly exceeds expenses, this may risk undue inducement for donation. In particular, compensation for sperm and oocyte donation is sometimes disproportionate, which raises further ethical issues beyond the additional risks for oocyte donation.

7. Exchange of services has been offered for donation in some countries, especially for obtaining oocytes, where IVF cycles, (or rarely) female sterilisation are provided without charge in exchange for oocytes. This raises the concern of undue inducement for donation, which means that appropriate consent is not obtained. Furthermore, this creates a conflict of interest for a donor that could lead to withholding of information that would make her unsuitable as a donor. Because an IVF patient undergoes the risk of ovarian stimulation, the added risk for additional donation may be minimal but must be considered. In any case, obtaining oocytes from a source abroad, especially from resource-poor countries, where one cannot check the standard of protection of the donor, is unethical, and presents the danger of abuse.

8. Gamete and embryo donation may be intended to be anonymous or
not. Careful counselling that acknowledges the potential of the child identifying his/her genetic origins is essential. If donation is between friends or family members, the risk of undue influence affecting the decision to donate exists. In addition, anonymity of the donation may be more difficult to ensure in this setting. The more direct the donation, the higher the chance of the offspring obtaining knowledge about his/her origins in the future, whatever parental intentions are regarding confidentiality. Even if the intention of the recipient is not to inform the child, there is always a risk of the origins being revealed unintentionally or in situations of disagreement in the family in a way that is not in the child’s best interests.

9. Many countries have specific legislation pertaining to gamete and embryo donation, making clear the legal parental status of the intended parents and the lack of legal responsibility of the donor(s). Otherwise, the prospective recipients and donors may seek independent legal advice, and enter into a consent agreement that outlines the critical issues involved and delineates the intended rights and responsibilities of all parties.

10. Several models exist internationally with regards to anonymity of the gamete donors; in some countries this is compulsory (and guaranteed for donors), whilst in others, donors must undertake to give their identity to the offspring at legal maturity if/when informed by their legal parents. Although a culture of openness has replaced that of secrecy over recent years, at least in some countries, there is no available research to firmly prove the superiority of one model over the other. Direct donation, for instance from friends or family members, is also possible.

11. With familial donation, donation between siblings raises the least confusion, whilst donation from gestational parents to child or especially child to parent raises the most.

12. A major issue in all gamete donations is protection of the interests/welfare of the potential child, as well as of those of the recipient(s) and the donor and his or her partner. The relation between the biological and social parents may be enshrined in law, whenever donation is permitted.
Recommendations

1. No genetic material should be used for donation without appropriate screening and quarantine, and the formal written consent of the recipient(s), after appropriate counselling on the implications, and full explanation of the local legal effects. Withdrawal of consent may be appropriate until the gametes or embryos are used, but not after use.

2. The number of donations from any single donor should be limited in order to avoid the danger of genetic consanguinity and/or biological incest among offspring.

3. Use of donated genetic material to extend the natural reproductive lifespan of women must take into account the significant potential risk to the individual woman as well as the offspring. Counselling about the potential influence of parental age on child development must be included.

4. Donation should be unpaid and only reasonable reimbursement of expenses incurred in donation given, in order to avoid commercialisation of reproduction and undue inducement of donors.

5. The potential donor and the recipient should be encouraged to address the question of eventual disclosure to the child with appropriate counselling.

6. The management of donated gametes and embryos should be regulated by a professional or governmental authority.

7. Donation of genetic material should be altruistic and free from commercial exploitation. Reasonable compensation for legitimate expenses is appropriate. Exchange of services (egg sharing) should only be permitted in a system where no financial gain is possible for the donor.

*Lyon, June 2007*
GUIDELINES FOR THE USE OF EMBRYONIC OR FETAL TISSUE FOR THERAPEUTIC CLINICAL APPLICATIONS

The use of embryonic or fetal tissue or cell transplants for improving or curing disease should be regarded according to the rules applicable to therapeutic transplantation in general. The procedure for harvesting fetal tissue and the research related to it should be permitted. The issue of therapeutic tissue or cell transplantation is not part of the abortion debate. Although tissues can be obtained from induced termination of pregnancy as well as from spontaneous fetal loss. The procurement of the fetal tissue should be subject to local legislation and regulation, which understandably varies among different countries.

In countries where use of these tissues is legal, the following guidelines are suggested to help ensure that in the circumstance of a woman’s decision to terminate a pregnancy, there is no undue influence due to the potential for subsequent use of donated embryonic or fetal tissue.

1. A final decision regarding termination of pregnancy should be made prior to a discussion regarding the potential use of embryonic or fetal tissue for research or for therapeutic clinical applications.

2. The decision regarding the techniques proposed for induced termination of pregnancy should be based solely on concern for safety of the pregnant woman.

3. The recipient of the tissues should not be designated by the donor.

4. Embryonic or fetal tissue should not be provided for financial gain.

5. The physicians providing pregnancy terminations should not be allowed to benefit from the subsequent use of the embryonic or fetal tissue. Informed consent should be obtained from the woman alone for the use of embryonic or fetal tissue for research or for therapeutic clinical applications. Any proposed research must be conducted under the direct review of any local or national ethics committees.

Lyon, June 2007
TESTING FOR GENETIC PREDISPOSITION
TO ADULT ONSET DISEASE

Background

1. Predisposition genetic testing for adult diseases presently covers a wide range of diseases, from a high likelihood of fatal disease to those in which only a slight increase in risk for highly treatable diseases can be predicted. The ability to test for multiple predisposition to adult diseases and conditions (such as obesity) is rapidly expanding. The accuracy of most genetic diagnoses in predicting actual disease is still developing or unknown at present.

2. How these predisposition tests will be used to benefit patients and how harms such as social and economic discrimination based on such testing can be prevented, are of ethical concern. The likelihood exists of social discrimination based on tests that define different groups in society (for example, those with and without certain predisposition genes) given the propensity of cultures to define social acceptability on a multitude of preventable and non-preventable characteristics. This information can also be used to calculate risks for disease onset that may influence marriageability and employability, as well as insurability. Because of these broad risks, national and international guidelines for ethical use of predisposition testing are appropriate.

3. Predisposition testing of children can be problematic because the choice they would make as adults to acquire such information is unknown.

4. Research regarding predisposition and development of genetic tests for predisposition offer unique issues concerning confidentiality, since access to the results may impact the health of individuals as well as their genetic families.

5. Access to predisposition testing raises unique issues in international health particularly when the critical gene was identified in a developing country’s population. If access to the information could make a major advance in quality and length of life (for example dependent on relevant life-style changes or prevention of exposure to certain medications with a diagnosis of enzyme deficiency) then there
is a corollary obligation to ensure access to testing for the population that provided the genetic information.

Recommendations

1. No predisposition testing should be done or offered in the absence of informed consent. Informed consent for predisposition testing is different from other diagnostic tests, given the complex genetic and environmental interplay that influences the appearance of the given disease.

2. Predisposition testing in childhood should be limited to those conditions in which treatment in childhood will significantly impact or ameliorate the presentation of disease.

3. Informed consent requires pretest genetic counselling by a trained genetics counsellor as well as follow up after testing (whether the predisposition was found or not). Significant personal and familial harm can occur if counselling is not provided in depth prior to testing. In particular, the influence of the information received, positive and negative, on choices and health care of genetically related family members needs to be explored with the individual patient prior to testing.

4. Confidentiality of the testing and of the results is critical. For circumstances where family members’ choices of their own testing may be predicated on the results of the individual tests, the confidentiality or release of information to affected family members must be determined prior to testing. Even if confidentiality is chosen, individual patients need to be counselled that their behaviour may give as clear a message to family members as revealing the diagnosis.

5. Researchers should offer individuals participating in research on predisposition tests an opportunity to state whether they would themselves desire information of the results, understanding that in many research settings the accuracy and meaning of genetic predisposition tests may be still developing. In addition, they should have the opportunity to designate whether or not genetically related family members should have access to the information if they so
desire, and if the information could significantly influence their health care.

London, June 2001

ETHICAL GUIDELINES CONCERNING CYTOPLASMIC ANIMAL-HUMAN HYBRID EMBRYOS

1. Stem cell research with embryos created by somatic cell nuclear transfer (SCNT) is an important tool for investigating disease behaviour at the cellular level and the possibility of cell therapy with the further aim of preventing rejection of the donated cells. The benefits are potentially much larger than those only in the reproductive field, with possible benefits for many common diseases like diabetes or Parkinson’s disease.

2. A major concern when embryos are created de novo for stem cell research is the source of the oocytes, whether or not for the purpose of enucleation and SCNT. There is a risk of coercion or undue inducement for women to donate oocytes for research from monetary or social rewards. The procedure also entails certain risks for the female (see guidelines on gamete donation and genetic testing).

3. Research with interspecies embryos may provide a means of pursuing research with enucleated cow oocytes and human somatic cell nuclear transfer. The resulting cytoplasmic hybrids (“cybrids”) may solve the problem of the scarcity of human oocytes donated for research, and the previously addressed dangers of coercion of and complications in vulnerable women.

4. Creation of such animal-human cytoplasmic hybrids raises serious ethical concerns as to the status of this “admixed embryo”.

5. A major societal concern is the eventual birth of such an entity, but it is unlikely that such an embryo could develop into a fully- or even partially-grown entity after uterine transfer.

Recommendations

1. Research on cybrid embryos should be encouraged, provided there is
no alternative. Restriction to a limited number of days for gestational development (14 for example) is an essential element of regulation of the use of these cybrids.

2. A hybrid embryo created for research must not be placed into a human uterus.

3. Somatic cell donors’ autonomy should be respected by informed and voluntary consent based on adequate information.

4. In the case of animal-human cytoplasmic hybrids, the information given in order to obtain proper consent from donors or their representatives should include elements of both the clinical and research protocol, including the fact that embryos may be created to isolate stem cells that may outlive the donors.

Paris, October 2008

PROFESSIONAL OBLIGATIONS RELATED TO DEVELOPMENTS IN GENOMICS AND PROTEOMICS IN HUMAN TESTING

Background

1. The growing knowledge base in human genetics based on sequencing of the genome, identification of genes and polymorphisms associated with risk for a range of human diseases, proteomics and epigenetics that influence the expression of those genes, all require continuing professional education as well as engagement in the development of ethical guidelines and legal regulations regarding these developments.

2. The discipline of Obstetrics and Gynecology has a heightened interest as the research has implications for every aspect of reproductive health. Prenatal, pregnancy, and interpregnancy care will affect fetal epigenetic programming.

3. Potentially, the ability to select embryos for use with the presence or absence of specific mutations can be used to both prevent fatal childhood disease, but also to avoid risk for highly treatable or modifiable adult disorders.

4. The growing knowledge base will continually challenge both our
present ethical concepts and the regulatory environment, and require reconsideration and potential modification of ethical guidelines and law.

Recommendations

It is recommended that Obstetrician/Gynecologists and their representative societies:

1. Actively engage with legislators, civil society, and the public in ongoing evaluation of development in this field, and with the implications for new or changing ethical guidelines and regulatory laws.

2. Ensure that the sensitive nature of this information be adequately protected through privacy and confidentiality regulations that impact on data collected through research or clinical venues.

3. Ensure that any testing done in a country, whether by the internet or on site, meets carefully explicated requirements for counselling as well as for data and tissue protection.

4. Ensure that use of biobanks and other tissue and sera repositories is regulated and has research requirements that protect confidentiality as well as represent the intent of donors to such banks.

5. Ensure that professionals who counsel or give advice regarding genetic issues must continuously refresh their knowledge to ensure that the advice they give is up to date and is adequately understood.

6. Avoid conflicts of interest related to marketing, and self-referral to direct consumer testing, and ensure that any direct testing follows all regulatory and ethical guidelines.

7. Specifically engage in development of international and national professional ethics guidelines for relevant areas of the profession, such as assisted reproduction, perinatal medicine, and gynecologic oncology.

Paris, October 2008
INTRODUCTION

1. In recent years there has been a dramatic increase in multiple pregnancies throughout the world. For example, some countries reported a doubling of twin pregnancies and the quadrupling of triplets over the last twenty years. The relative increase in higher order pregnancy has been even greater.

2. Undoubtedly, the main factor has been the use of ovulation inducing drugs and of multiple embryo transfer in the treatment of infertility. The increase in twin pregnancies may also be attributed in part to trends towards increased maternal age at conception.

3. The need for infertility treatment has also been rising sharply due to factors which include the impact of sexually transmitted diseases and the trend towards pregnancy at later age.

4. Multiple pregnancy has very serious implications for the mother and her offspring, for the family and the community, and for health service resources particularly where neonatal care services are limited or lacking.

RECOMMENDATIONS

1. Every effort should be made to prevent infertility through further research. Timely education and information about the risks and prevention of infertility are necessary. In addition, research and education are urgently required to improve the outcome of technologies of assisted reproduction.

2. The clinicians should take professional responsibility for optimising their own practices in the interests of avoiding multiple births.

3. Obstetrician-gynecologists have an important responsibility to make both the public as well as their patients aware of the many hazards associated with multiple pregnancy, especially with triplets and higher order pregnancies. In addition, they must make the public and their
patients aware that the high risk nature of multiple pregnancies requires an expertise that may not be available in some rural or smaller town areas.

4. Couples seeking treatment for infertility must be fully informed in writing of the numerous, complex and potentially far-reaching risks of multiple pregnancy, both to the woman and to her potential progeny. Counselling should also be available from experienced members of perinatal teams.

5. The misuse of drugs for the induction of ovulation is responsible for a great many of iatrogenic multiple pregnancies. Therefore, those using these drugs should be familiar with the indications for their use, their adverse side-effects, and the methods of monitoring and preventing iatrogenic multiple pregnancy.

6. Obstetrician-gynecologists using assisted reproductive technologies, whether by the induction of ovulation or the transfer of embryos, should aim to achieve singleton pregnancies. Under optimal conditions, single embryo transfer should be performed and good cryopreservation programmes should be available. International and national professional bodies have a responsibility to issue recommendations for good practice with a view to reducing the incidence of iatrogenic multiple pregnancy. Centres should be certified or accredited in order to ensure a uniformly high standard.

7. In order to monitor and regulate professional practice, audit of the use of these technologies should include not only the fertility success rate but also statistics on singleton live births, the incidence of multiple pregnancy, the maternal and perinatal mortality and morbidity rates, the incidence of preterm delivery and low birth weight, the occurrence of long term disabilities among offspring, and the use of fetal reduction. Couples should have access to reliable and standardized local centre statistics as well as national and international comparative statistics.

8. The risks for both mother and the resulting children from triplet and higher order pregnancies must be disclosed to and discussed with the couple. This discussion should include information about the availability, use and implications of fetal reduction.
 Clinics and clinicians, when discussing their results in public, must avoid describing multiple pregnancies as a success rather than a complication of treatment. The media should be aware that best professional opinion is to regard multiple pregnancies as a complication.

Multifetal reductions

Recommendations

1. Multiple pregnancy of an order of magnitude higher than twins involves great danger for the woman’s health and also for her fetuses which are likely to be delivered prematurely with a high risk of either dying or suffering damage.

2. Clinical priority should be a focus on careful planning and monitoring of infertility treatment for the reduction or avoidance of multiple pregnancies. However, where such pregnancies arise, it may be considered ethically preferable to reduce the number of fetuses rather than to do nothing.

3. Multifetal reduction is not medically considered as terminating that pregnancy, but rather as a procedure to secure its best outcome.

4. Information provided must include the risks to mothers and fetuses with and without fetal reduction, including spontaneous miscarriage. Whether the couple decide to maintain or to reduce high order multiple pregnancies, they should be assured that they will receive the best available medical care.

London, March 2005

ETHICAL ASPECTS OF GAMETE DONATION FROM KNOWN DONORS (DIRECTED DONATION)

1. The ethical issues concerning anonymous donation of gametes have been addressed.¹ These guidelines concur. Situations where the

recipients are selected by persons known to them (directed donation) are rarely taken into account in these documents.

2. Requests for directed sperm donation are infrequent due to the availability of advanced micromanipulative assisted reproductive technologies. In developing countries, however, the higher cost and limited availability of advanced technologies are reasons for requests of directed donation.

3. Requests for directed oocyte donation are increasing due to the limited number of donors and increasing number of women requiring oocyte donation for ovarian failure.

4. Directed donation may be requested for reasons that include the donor’s known health status, genetic makeup, character, and social and cultural background.

5. Many recipients of oocyte donations may have strong preferences regarding the use of anonymous versus directed donors. Recipients who use anonymous donors seem to be more likely to maintain privacy in contrast to those who choose directed donors.

6. The issues of confidentiality in directed donation differ from anonymous donation in that the facts concerning the genetic origin of the potential child are known not only by the health care professionals involved but also at least by the donor and the recipient. Confidentiality is therefore determined not only by legal rules and professional ethical standards but also by the relationship of the involved parties.

7. A major issue in known gamete donation is protection of the interests of the potential child as well as of those of the recipient(s) and the donor and his or her partner. In cases where the recipient(s) ask(s) for donation, the requirement of informed consent from the donor and the recipient(s) needs to address the specific problems that arise from the fact that both the donor and the recipient(s) know the genetic parent of the child. The relationship between the donor and the recipient(s) may be influenced by the donation in several ways.

8. Psychological evaluation and counselling should, if possible, be offered to the gamete donor and the donor’s partner. The potential
impact of the relationship between donor and recipient should be explored. The donor should be knowledgeable about any plans that may exist for the degree of disclosure and for future contact between donor, recipient(s) and the potential child.

9. The interest of the child calls for a profound discussion of the effects of this kind of family secret on the psychological development of the child. As the child’s genetic origin is known to both donor and recipient, the ethical dilemma of withholding this information from the child is even greater than in anonymous donation. Even if the intention of the recipient is not to inform the child, there is always a risk of the truth being revealed unintentionally or in situations of disagreement in the family in a way that is not in the child’s best interests. The potential donor and the recipient should therefore be encouraged to address the question of eventual disclosure to the child before entering into the intended procedure.

10. The prospective recipients and donors should be encouraged to seek independent legal advice. They should be encouraged to enter into a consent agreement that outlines the critical issues involved and delineates the intended rights and responsibilities of all parties. The disposition of all unused oocytes should be agreed upon.

11. Known gamete donors should be subject to the same screening standards that apply to other gamete donors. Recipients of gametes from known donors should not have the option of waiving particular screening tests. The potential donor should have the right to retain confidentiality of the results of the screening. The recipients should not be informed that full confidentiality may be difficult as the recipients know about the screening and may assume there is a health risk issue if the donation is not possible.

12. Informed consent to a directed donation should be undertaken without the presence of the recipient. Physicians should attempt to determine whether known donors are motivated by undue pressure, coercion or financial benefits; in such a case, the physician should decline to proceed with the donation.

13. Informing children resulting from directed gamete donation of their genetic origins is an important protection against inadvertent
consanguinity. The physician should ensure that the donor is not a blood relation of the recipient to a degree that would constitute biological incest.

London, May 2000

SURROGACY

Background

1. Surrogacy describes a reproductive model where a woman carries a pregnancy and delivers a child on behalf of a couple in which a woman is unable to do so, for instance because of a congenital or acquired uterine abnormality, or because of a serious medical contraindication to pregnancy.

2. In all cases, the intention is that the surrogate will relinquish the born child to the commissioning couple.

3. Some societies have strong reservations about the practice of surrogacy, and make it illegal. In other societies the process is supported by specific legislation, enabling the commissioning couple to become the legal parents.

4. In practice, surrogacy may involve a woman with no genetic link to the future child, where the embryo is conceived by IVF with the gametes for instance of the commissioning parents (or full surrogacy), or a woman also provides her oocytes (or partial surrogacy), or is related to one of the intended parents. Possibilities include the addition of gamete donation in either case.

5. Surrogates undergo risks during pregnancy, similar to those of any other pregnant woman (miscarriage, ectopic pregnancy, common pregnancy complications), which may be increased by the risk of multiple pregnancy when IVF is used to create the embryo(s). Psychological reactions may complicate this further with depression on surrendering the child, grief, and even refusal to release the child.

6. The commissioning parents are suffering from intractable inability to
conceive, and generally consider this is their last chance at achieving parenting with a genetic link of one or both parents to the offspring.

7. There has been only short follow up and psychological study of children born by surrogacy, and of the families involved, including the impact on any natural child(ren) the surrogate may have. Potential harms for the offspring include the sequelae and complications of multiple pregnancy on surviving children, as well as the issues of gamete donation (anonymity or openness) on the psychological well-being of the child. Clarification of the legal standing of the surrogate mother, also known as the gestational mother, as well as of the commissioning parents, should be addressed carefully prior to any gamete or embryo transfer. In particular, abandonment of the child by the commissioning parents and/or gestational carrier, in case for instance of unexpected complications or birth defects, must be addressed before conception.

8. In general, compensation for expenses directly related to the pregnancy, and loss of income due to the pregnancy, is accepted. Disproportionate payment given to surrogate women risks undue inducement of vulnerable women, and has the potential to lead to commercial exploitation, in particular recruitment of women of underprivileged background. There is also the issue of familial coercion: separate counselling of the prospective surrogate mother and commissioning parents is essential.

9. Contracts are often drawn between commissioning parents and the surrogate, engaging all parties’ responsibilities: the surrogate to behave responsibly during pregnancy in order to minimize the risks for the future child, with regard for instance to usual nutritional advice and antenatal screening; and the future parents to undertake their parental responsibility to that child whatever the circumstances and health, in case for instance of congenital abnormality.

10. In some jurisdictions, the surrogate who delivers the baby may have the right to keep the child, even when parental rights are legally transferred to the commissioning parents. Furthermore, she also has legal rights during her pregnancy, where her bodily integrity is paramount. Appropriate counselling of all parties is again essential to ensure all parties are aware of their responsibilities as well as of their
rights in the agreement they undertake, recognising that the welfare of the future child is in the equation.

11. Openness about the mode of conception in all methods of assisted reproductive technology (ART) has become more common since their inception, with no evidence of detriment, and with the advantage of avoiding the revelation of secrets in moments of stress or distress, and the added possible interest of the child to be aware of his/her genetic background. The added complexity of partial surrogacy compared to full surrogacy, where the commissioning parents are also the genetic parents, means that full surrogacy is the preferable option.

12. It is generally accepted where surrogacy is legal, in order to avoid conflicts of interest that might create undue pressure or coercion, that different medical teams should look after the commissioning parents undergoing IVF, and the (intended) pregnant surrogate.

Recommendations

1. Surrogacy is a method of ART reserved solely for medical indications. It is unacceptable in principle for social reasons.

2. Because of the possibility of psychological attachment of the surrogate to her pregnancy initiated on behalf of others, only full surrogacy is acceptable. Furthermore, all efforts must be undertaken to reduce the chance of multiple pregnancy with the ensuing risk to the surrogate mother and future babies.

3. The autonomy of the surrogate mother should be respected at all stages, including any decision about her pregnancy that may conflict with the commissioning couple’s interest.

4. Surrogate arrangement should not be commercial, and are best arranged by non profit-making agencies. Special consideration must be given to trans-border reproductive agreements, where there is increased risk of undue inducement of resource-poor women from resource-rich countries’ citizens.

5. The commissioning couple and potential surrogate must have full and separate independent counselling prior to their agreement, and be encouraged to address the question of eventual disclosure to the child
before entering into the intended procedure. Counselling must include the risks and benefits of the technique to be used, and of pregnancy, including prenatal diagnosis. Such counselling should be factual, respectful of the woman’s view, and non-coercive.

6. Where there is no national legislation, prospective parents and the surrogate should be encouraged to seek independent legal advice. They should be encouraged to enter into a consent agreement that outlines the critical issues involved and delineates the rights and responsibilities of all parties. The disposition of any unused embryos should be agreed upon.

7. Surrogacy, if conducted by individual physicians should be approved by an ethics committee and should be practiced strictly under medical supervision.

8. When the practice is performed it should take full regard of the laws of the jurisdiction concerned, and participants should be fully informed of the legal position.

9. Research about coercion and harm to collateral individuals, such as existing children of the surrogate, must be conducted to understand the harm or benefits of this reproductive model.

Lyon, June 2007

PRENATAL DIAGNOSIS AND SCREENING

Background

1. Prenatal screening and diagnosis have become part of the routine antenatal care of pregnant women in resource-rich countries.

2. The techniques vary, but many services offer first trimester screening (bloods and ultrasound scanning), and a second trimester anomaly scan. Chorionic villus sampling (CVS), amniocentesis and cordocentesis are also possible, and are used for diagnosis rather than screening.

3. Preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) are more recent forms of prenatal testing that are
performed on the embryo in vitro, that is, at an even earlier stage than antenatal screening, before a pregnancy is established. They may be used when there is a known genetic disease in the family for which diagnosis is available. They necessitate the technique of IVF, with the creation in vitro of several embryos for testing and the aim of transferring an embryo free of the specific genetic anomaly for which testing was sought.

4. Recent advances have been numerous, and include increased accuracy of ultrasound scanning, and the possibility of non-invasive prenatal diagnosis (NIPD) techniques on maternal blood, which measure fetal DNA or RNA in the pregnant woman’s blood from 6/8 weeks of gestation. For the time being, this technique is mostly used for sex determination for sex-linked disease and diagnosis of rhesus disease.

5. The information obtained by all techniques may lead to reassurance about an ongoing pregnancy, termination of pregnancy, the non-transfer of an affected embryo in an IVF cycle, or to adjustments in future life-style. Indeed, a potential benefit of prenatal screening and diagnosis is the possibility of a legal termination of pregnancy when the woman so desires, or the possibility of preparing for the birth of a child born with a serious disease.

6. When a pregnancy is terminated on the grounds of likelihood of serious disease of the fetus, or an affected embryo is not transferred after PGD, there is a potential danger of the implied discrimination against living persons affected by the very abnormality which led to the termination of pregnancy or non-transfer of the embryo. Most families do not share this prejudice, but prefer to have a healthy child. Pregnancy termination or non-transfer of affected embryos has been chosen by some parents who feel that the burden of serious disease imposes a weight of suffering for the child that is intolerable for them, often having seen the suffering of another child affected by the same disease process.

7. Procedures for prenatal diagnosis such as chorion villus biopsy, amniocentesis, and cordocentesis present risks to the fetus, with a small risk of miscarriage. Another risk with all techniques is the occurrence of false positive or negative results, which should be
carefully audited by outcome diagnosis following birth or abortion. A similar audit should be used for PGD and NIPD.

**Recommendations**

1. Prior to agreeing to antenatal screening and/or diagnostic procedures, women must be informed and counselled, in terms that are evidence-based and respectful of the women’s views, about the risks and benefits of the proposed techniques, and their liability to produce false positive and negative results. If available, the alternative of IVF must mention the specific burdens and risks specific to the technique.

2. Women should not be denied the availability of prenatal diagnosis because they will not agree in advance to pregnancy termination as an option. Nor should the techniques be withheld on social or financial grounds.

3. Prenatal diagnosis may result from the deliberate use of a specific diagnostic procedure or from routine pregnancy screening and surveillance using ultrasound or other screening tests. The need for counselling and consent applies equally to the use of all techniques.

4. Women consenting to the use of prenatal diagnostic procedures should be asked in advance whether they want any ensuing information to be withheld from themselves and/or others during the remainder of the pregnancy. Such information may concern, for instance, the sex of the fetus, or a specific possible disease or malformation.

5. All information acquired from prenatal screening and diagnosis is confidential to the pregnant woman. She alone may decide about the future of her pregnancy within the limits of the law. In ideal cases, she will share this information with the future father so that they may make a joint decision about the future of the pregnancy.

6. Information of the sex and status of the fetus, when it is available, should be made accessible to all prospective mothers requesting it. However, sex selection is of particular ethical concern when it is driven by value differences ascribed to each sex or arises from pervasive gender stereotypes (see the Recommendation on Sex Selection for non-medical purposes).
7. Standard medical care or services during pregnancy and delivery should be made available to all women, including when an abnormality has been diagnosed.

8. Equity requires that these important diagnostic services are made as widely available as possible.

London, March 2012

ETHICAL ASPECTS OF HIV INFECTION AND REPRODUCTION

1. HIV infection is a transmissible disease with profound social and psychological implications for the woman, her partner and her family as well as for the health care team and society. Its characteristics include a prolonged latent period, very high rates of morbidity and mortality unless appropriately treated, and social stigma. There is as yet no vaccine or curative treatment, but under medical management, its effects are of a serious chronic infection, with controlled symptoms. HIV-infection can be sexually transmitted, and infected persons are liable to infect all of their sexual partners. Vertical transmission from mother to fetus, or to infant via breast milk may also occur. The incidence of this vertical transmission is reduced by drug therapy.

2. These facts bring sharply into focus the ethical conflict between patient privacy and confidentiality and the need to protect the sexual partners, the health care team and the public from a serious and, if untreated, a disabling and ultimately fatal communicable disease.

3. Because the disease has the potential of reaching epidemic proportions, the overriding consideration of infection control for the whole population comes into conflict with the limits of individual rights. Moreover, besides aggressive educational programmes, other measures that may be considered would be mandatory offering of antenatal screening and confidential disclosure of HIV status to sexual partners and to health care workers at risk of exposure. Information regarding numbers of seropositive individuals should be made available to public health officials.

4. Individuals who are informed of positive serostatus may suffer severe
psychological sequelae including at its worst the sense that they have been given a death sentence. Furthermore, discrimination based on seropositivity in regard to housing, jobs and insurance exists. Physicians have a duty, therefore, to provide not only individual counsel, reassurance and care for patients but also public advocacy to protect them from unfair and punitive actions.

5. While appreciating the importance of confidentiality and patient privacy, the ethical responsibility of individual patients to prevent harm to others still exists. Informed consent must be obtained prior to testing for HIV infection and communication of the resultant information. Every effort should be made through counselling to convince individual patients of their responsibility to others including the importance of allowing such information to be used to protect sexual partners and health care workers. If in spite of every effort, consent is not obtained and the risk of transmission is high in certain circumstances, with consultation, it may be justified to override patient confidentiality.

6. Assisted reproductive technology requires the elective donation of gametes, embryos or surrogate carriage of pregnancy. In view of the elective nature of this technology, confidential counselling and testing of prospective donors and surrogate carriers should be undertaken, with inclusion of only those with negative HIV status, in order to protect the interests of those at risk of unwanted exposure to HIV, including potential children.

7. Breastfeeding: In societies where safe, affordable alternative methods of infant feeding are available, it may be unethical for an HIV infected mother to breastfeed her child. Where the risks of alternative infant feeding are high, the balance of risk to the infant may make breastfeeding ethically justified. See the FIGO Committee for Safe Motherhood and Newborn Health guidelines, IPA, ICM, and FIGO joint statement on breastfeeding, including breastfeeding by HIV-infected mothers.¹

London, March 2012 (updated)

HIV AND FERTILITY TREATMENT

Background

1. The WHO estimated that by 2009, 33.4 million people worldwide were living with HIV, of whom over half are women, mostly of reproductive age. The development of effective antiretroviral (ARV) regimens leading to a major increase in the life expectancy and life quality of HIV infected persons, together with a significant reduction in the perinatal transmission of the virus, has changed the reproductive limitations of patients with this serious viral disease.

2. The mother to child transmission (MCT) risk can be reduced from 15–35% to below 2% with ARV treatment, particularly during the third trimester, with a carefully timed and planned mode of delivery.

3. In resource rich countries, a unique aspect of the success of ARV treatment has been a sharp rise in the number of HIV infected men and women seeking assisted reproduction and advice on how to conceive safely. Assisted reproduction for HIV couples should currently be restricted to specialised centres. However when the infection advances to AIDS, the prognosis and risks become so serious that assisted reproduction should not be considered.

4. The fact that the greatest burden of HIV falls on countries that cannot afford the benefits of ARV treatment is of grave ethical concern. In resource poor countries this may be compounded by the unavailability of basic medical services. Furthermore in these countries the risk of transmission from patient to health personnel or vice versa and mother to child transmission is even graver in view of the limited availability of services that prevent transmission.

5. Several factors are to be considered when decisions are made about the provision of infertility treatment to infected couples. These include horizontal transmission risk to the uninfected partner, life expectancy of the infected individual, patient compliance, high risk behaviour and life style issues, and support network if the infected individual becomes seriously ill or dies.

6. Education about viral transmission and prevention is essential, including the education of service providers/advisers and laboratory
personnel. Education about known preventive measures such as protected intercourse at all times, intra uterine insemination with washed sperm, or other techniques if warranted by relative infertility, is important.

7. Facilities may consider having separate rooms and laboratories for HIV-infected and non-infected patients, taking account of the additional burden on resources, and the need to prevent identification and stigmatization of HIV-infected patients.

Recommendations

1. Efforts must be made to convince all women and men of reproductive age of the medical benefits of knowing their HIV status.

2. It is essential to offer appropriate advice to women (and men) with HIV or whose partners are HIV positive who wish to reproduce, so that their health, the health of their partner, and that of any future children is protected. Treatments of seropositive couples by assisted reproductive means, which reduce the chance of exposure to the women and their offspring, are of proven efficiency, and it is therefore ethical to offer such techniques in appropriate cases.

3. Access to ARV treatment and to assisted reproductive techniques of all populations suffering from HIV, and of seropositive patients, must be promoted on an equitable basis.

4. Any restriction on access to assisted reproduction should be clearly justified and not based on discrimination. Women, including sex workers, have the human right to make choices about their sexual behaviour.

5. Public information and access to means to prevent HIV transmission for women and men at all stages of their reproductive lives are of utmost importance and need to be a concern of all member organisations and individual practitioners.

6. Prevention – by providing information about high risk behaviour – is essential. The need for responsible behaviour to avoid spreading the virus and prevent its transmission to the future child, including the
necessity to accept ARV treatment during pregnancy, must be highlighted.

7. Health care providers should ensure that they, their colleagues, and laboratory personnel have the training and means to take, and then actually take, due precautions to prevent the spread of HIV-infection to others, and to non-infected laboratory samples. Seropositive health care providers have an obligation to ensure that they engage in no behaviour that puts patients at risk.

London, March 2012 (updated)

ETHICAL CONSIDERATIONS WITH OOCYTE AND OVARIAN CRYOPRESERVATION IN WOMEN

Long-term survival from cancer treatment in childhood and during reproductive years in women is becoming common, with a consequent desire to retain fertility for future childbearing. While in vitro fertilization and storage of embryos is possible for a small proportion of these women with partners and the financial resources to make this choice, the increasing success of oocyte and ovarian cryopreservation and transplantation offer the potential of a broader range of options in the future.

The underlying issues of access, cost and efficacy that arise in sperm donation also need to be considered for ovarian and oocyte cryopreservation. The issue of unduly inducing hope in cancer treatment, such as that an individual will survive to be able to contemplate their own reproduction, is ethically problematic for adults making their own choices. The ethical problems are compounded when parents attempt to make these decisions as surrogates for their children.

Treatment of the cancer is the primary medical goal, and risks of delaying treatment in order to induce ovarian stimulation and retrieval, or ovarian removal or transplant, must be carefully considered, and should not have a significant impact on treatment.

Assessment of long-term success of fertility preservation will be dependent on the nature and length of cancer treatment. Some treatments that result in uterine radiation or removal of the uterus leave the individual with
surrogacy as the only means for gestation of a pregnancy resulting from their gametes. This must be taken into account at the time that these techniques are discussed.

Recommendations

1. The most available, standardized and effective technique should primarily be offered, such as IVF or embryonic freezing, if the reproductive status of the woman makes any of these feasible.

2. Cryopreservation of oocytes and ovarian tissue represent uncertain efficacy at present. Access to such innovative techniques should be limited to carefully designed research settings where efficacy and outcomes can be assessed.

3. In procedures where there is as yet inadequate experience or research to assess success, physicians have a heightened obligation to frame the benefits and risks in such a way that the parents and individual understand that the hoped for benefit may never be achieved.

4. Physicians have an obligation to advance research into the success, efficacy and potential risks – such as transmission of malignant cells in the cryopreserved tissue – in oocyte and ovarian cryopreservation.

5. Clarity about the costs, including for long-term storage, and time lines for use or destruction, should be developed and communicated at the initiation of consideration of these options.

6. Cancer can occur at any stage of a person’s life. It is therefore important that there is clarity as to the consent provisions relevant to cryopreservation. First, cancer may affect adults. In these circumstances, the person herself has the right to offer or withhold consent to cryopreservation, so long as she is legally competent to make that decision. When the adult is not competent, unless the law provides for a proxy decision-maker with appropriate authority, it will not normally be permissible to remove and store tissue. When the person is a very young child, it is for the parents to make treatment decisions that are in the best interests of the child. Whether or not the possible preservation of future reproductive capacities is in fact in the child’s best interests will be a matter of judgement. Parents have to balance the immediate risks of recovery of ova or ovarian tissue
against the benefit that preservation of future reproductive choice might afford their children. When tissue is removed and stored, the young person, on reaching sufficient maturity to decide, should be offered information as to disposal options. Where the person with cancer is below but approaching legal capacity, it cannot always be presumed that she is not able to make her own decisions. Mature young people are often in the best position to make their own decisions, and should be permitted to do so if they are able to understand the relevant information and to use it to make a decision.

7. Since cancer can occur at any age, clinicians must be particularly sensitive to the issue of capacity to consent to cryopreservation under legal requirements.

8. The desire to have future children is not limited to those with the financial and geographical means or opportunities to access these procedures. Physicians have an obligation to build an evidence base for the development of funding policies.

London, March 2005

ETHICAL GUIDELINES ON IATROGENIC AND SELF-INDUCED INFERTILITY

Background

1. Iatrogenic infertility is infertility caused by a physician’s actions, including reactions from prescribed drugs and from medical and surgical procedures. Infertility can also result from harm induced by others, including the patient herself.

2. Harmful practices and improper management of various medical conditions such as female genital mutilation, obstetric fistula, folk methods of treatment of infertility, hydrotubation and unnecessary pelvic surgery may result in pelvic adhesions causing iatrogenic infertility.

3. In developed countries, iatrogenic infertility is estimated to cause about 5% of male and female infertility. In developing countries, it is expected that the incidence of iatrogenic and self-induced infertility
would be higher than in developed countries. This may be due to some traditional practices and folk methods for treatment of infertility, such as female genital mutilation, and a higher prevalence of obstetric fistula and sepsis following various diagnostic and therapeutic procedures for infertility, such as intrauterine insemination and in some cases of oocyte pick-up in assisted reproductive techniques.

4. Iatrogenic infertility may occur as a side-effect of management of various obstetrical and gynecological conditions such as hysterectomy for post-partum hemorrhage, extensive curettage, radio therapy and chemotherapy for various malignant diseases during childhood or reproductive age, extensive surgery for benign or malignant diseases of the uterus and the ovary, post-operative adhesions following pelvic surgery, and extensive ovarian drilling for patients with polycystic ovarian syndrome.

Guidelines

1. Iatrogenic infertility may, in some circumstances, be unavoidable and occur as a side-effect of necessary surgical or medical procedures. It is the duty of obstetricians and gynecologists to take all necessary measures to reduce the incidence of iatrogenic infertility in such cases. Obstetricians and gynecologists should ensure that women are aware of this risk.

2. Gynecologists and surgeons performing pelvic surgery on girls or young women of reproductive age should remember that applying microsurgical techniques and precautions, whenever performing endoscopic or conventional pelvic surgery, minimizes the incidence of pelvic adhesions.

3. Gynecologists and surgeons should also remember that all diagnostic and therapeutic infertility procedures, however simple they are, should be performed under a complete aseptic technique.

4. Though adhesion-prevention barriers are capable of reducing adhesions after surgery, they do not completely eliminate the formation and reformation of adhesions. Medical research for the
prevention of adhesion formation and reformation should be encouraged.

5. Patients with postpartum hemorrhage should be offered, if possible, such alternative treatment as prostaglandins, ligation of uterine or iliac vessels, embolization of the uterine vessels, or D Lynch suture before finally being subjected to hysterectomy.

6. In young women who have not completed their families and suffer from various benign diseases of the genital organs, conservative therapy and fertility-sparing surgery and techniques should be applied whenever possible.

7. Patients with early malignant diseases of the reproductive organs who have not completed their families should be counseled on alternative fertility-sparing surgery based on the existing evidence in this field. Should they choose fertility-sparing surgery or medication, close follow-up of these patients should be arranged.

8. Measures should be taken to prevent risks of premature ovarian failure. Prevention may be achieved before the use of radiotherapy or chemotherapy for malignant conditions, by ovarian transposition or cryopreservation of embryos, oocytes or ovarian tissue. If available, subsequent auto-transplantation of any cryopreserved–thawed ovarian tissue, embryos or gametes should be discussed with the patients and/or guardians, including evidence-based risks.

9. Every effort should be made to improve standards of obstetric care provided to pregnant women, particularly in resource-poor regions. Improvement of antenatal and intrapartum care of pregnant women and availability of emergency obstetric care will help to prevent obstetric fistulae, which would reduce iatrogenic infertility.

10. Empowerment of women, and health education of the public, particularly school-age girls, on various issues of reproductive and sexual health, premarital counselling, dangers of folk methods, unsafe abortion, obstetric fistula and female genital mutilation, will also help to reduce iatrogenic and otherwise-induced infertility.

London, March 2006
FERTILITY CENTRES AND WHOM THEY SHOULD TREAT

Background

1. It is a particularity of fertility treatments that the existence of another person (the future child), whose welfare should be taken into consideration, is planned and hoped for. This means that a patient’s autonomy is balanced with the responsibility towards the future child.

2. A patient’s autonomy may clash with the welfare of the future child in rare instances. Such instances include aspects of the patient’s or her partner’s past or current circumstances that are likely to lead to an inability to care for the child to be born, throughout childhood.

3. Such aspects might include: mental or physical conditions, such as chronic or life-threatening disease (such as HIV, cancer, genetic conditions), or drug and alcohol abuse or dependency.

4. Another aspect is the likelihood of the future child suffering from a serious medical condition, including a genetic condition.

5. The help of a multidisciplinary team including counselors may be needed. The welfare of any existing child who may be affected by the planned birth should also be taken into account before providing any treatment services.

6. No licensed treatment is expected to be given to any patients without their written consent to that specific treatment. Written consent is obtained after explaining the nature and practical aspects of treatment, and ensuring patients’ understanding. In case of disagreement after initiation, the treatment should be discontinued.

Recommendations

1. Decisions about treating or refusing to treat patients should reflect the balance between patients’ autonomy, and the clinical team and patients’ responsibility to the future children.

2. Services should not be provided to anyone who is incapable of giving a valid consent, or has not given a valid consent to examination and
treatment, or storage and use of gametes or reproductive tissues when required.

3. Fertility centres should treat all requests for assisted reproduction equally without discrimination, such as marital status or sexual orientation.

4. Clinicians should be encouraged to refuse to initiate a treatment option they regard as futile, provided that they have informed the patient that they regard the option as futile.

5. Welfare of the future child should be regarded as an essential concern, which may mean not accepting a prospective patient’s request for treatment. It is unethical purposely to create a child with a disability, and centers may refuse such requests.

6. Clinicians should be encouraged to refuse to initiate any treatment option they regard as having a very poor prognosis, provided that they fully inform the patients and offer information about referrals, if appropriate.

7. Ensuring high success rates by not treating patients with poor prognoses should be regarded as unethical, although age may be used as a cut-off criterion, especially in publicly funded health care systems, when a poor success rate makes the treatment almost futile.

Paris, October 2008

UTERINE TRANSPLANTATION

Background

1. The overall prevalence of uterine factor infertility is approximately 3–5% of the general population. Adoption or surrogacy are available to overcome childlessness in this group. However, there is a group of women for whom adoption or gestational surrogacy is forbidden for personal, societal or religious reasons. For these women, uterine transplantation may offer an option for fertility achievement in the general population.

2. Pilot animal research on stable long-term large animal allografts for
investigating immunosuppressive regimens has documented successful pregnancies after syngeneic uterine transplantation in animal models such as mice, dogs, ewes, sheep, goats, and pigs. Recently, nonhuman primates and sheep models, with anatomy analogous to that of humans with notable exceptions, have been successfully used to further investigate the possibility of human uterine transplantation.

3. This research from multiple groups throughout the world has made it a topic for ethical debate, as it may be followed in humans should it prove successful. The uterine recipient and her partner will be the genetic parents of the child to be born.

4. Uterine transplantation is not a life-sustaining procedure, unlike other organ transplantation. It does not offer an improved survival and quality of life. It furthers a patient's wish in bearing her own biological child, with substantial potential risk to both mother and child.

5. The donated uterus, if removed from a living donor, necessitates relatively major surgery, with its own risk of complications.

Guidelines

1. Uterine transplantation, which may reach the human clinical experimentation stage, should occur only after significant and adequate research in appropriate large animal models including primates.

2. The lengths to which some women will go to experience uterine transplantation, even with the availability of such options as adoption and surrogacy in some cultures, can lead to a conflict of interest and pressure on researchers prematurely to move to human application.

3. It is unethical to remove a uterus for transplantation from a young woman who has not completed having her desired number of children, or a uterus with a deformed cavity.
4. Given the lack of data on safety, and the known hazards to live donors, the procedure is considered as ethically inappropriate.

Paris, October 2008

PREGNANCY AND MATERNAL/FETAL ISSUES

BRAIN DEATH AND PREGNANCY

Background

1. Brain injury in a pregnant woman most commonly results from either trauma or intracranial abnormalities such as an aneurysm that ruptures, causing hemorrhage or stroke. These casualties may lead to maternal brain death.

2. Brain death implies absolute and incontrovertible cessation of total brain function, including brain stem function. Supportive interventions are mandatory if somatic functions are to be preserved, in particular ventilation and circulation. A pregnant woman who has been diagnosed as brain dead is considered dead, and somatic support is justified only to design appropriate strategies for the sake of the fetus, if it is expected to be generally normal at birth and free from severely disabling physical and/or mental handicap.

3. Pregnancy adds considerable complexity to these rare conditions. Maternal supportive care may last as long as 15 weeks, far longer than the hours or days required for supportive care for organ donation. Once continuation of pregnancy has been decided after maternal brain death, systemic vital functions must be actively supported to maintain a maternal milieu as close as possible to the physiological state of pregnancy. The justification of such a perilous endeavour is not only to allow the woman to give birth to a viable neonate, but also to secure the neonate’s own brain integrity.

4. Neurogenic maternal pulmonary consequences may occur, requiring positive end-respiratory pressure and high concentration of inspired oxygen whose prolonged effect on the fetus is unknown. Hypotension develops in the vast majority of brain dead patients
requiring vasopressors which may cause dramatic decrease in placental perfusion.

5. Loss of central thermoregulation may lead to either hyperthermia or hypothermia, which are potential causes of fetal death or severe fetal growth retardation. Total parenteral nutrition through a subclavian line, required to ensure adequate caloric supply and normal fetal growth, may risk maternal sepsis. All of these may have deleterious effects on fetal growth and survival.

6. The decision about whether attempts to maintain pregnancy are likely to be successful depends first on the gestational age of the fetus. For brain death in early pregnancy, supportive care may lead to the birth of a desperately premature neonate. However, starting at 12–14 weeks of gestation, fetal survival has been successfully prolonged for 15 weeks, bringing the fetus beyond the threshold of viability.

7. During pregnancy, medical care may suddenly fail to support organ survival, for instance because of an irremediable cardiovascular instability. Pregnancy must then be interrupted, entailing the questions of potential fetal damage and the justification of an emergency delivery.

8. Pregnant brain dead women are diversely perceived by medical care givers as pregnant patients, terminally ill patients, dead persons, cadavers, or cadaveric incubators. They are not out of range of any harm or wrong, such as indignity, that could, consciously or unconsciously, be inflicted on them.

9. Just after delivery, brain dead women are disconnected from life support. Dying is a continuous process that culminates in brain and body function death. When life functions are artificially maintained by supportive care, death of individual persons can precede their physical dying. Prevented from dying, the brain-dead pregnant woman is not supported for her own good, but for the sake of someone else, her fetus. Therefore, her body is at risk of being used as a means to an end, as an object, or as an instrument.

10. For brain death during pregnancy, advance directives concerning the future of the fetus are rarely available, and a substitute has to decide according to their best understanding of the likely decision the brain-
dead person would have made. In the absence of an appointed substitute decision-maker, the person thought to be the most relevant substitute is a next of kin; that is, the spouse or the companion, an adult child, one or both parents, or other relative. Only when the choice of a substitute among the relatives seems insoluble, e.g. the father of the child is neither the spouse nor the companion, or when substitutes of equal standing disagree concerning the prolongation of pregnancy, a court may be asked to decide, or a guardian may be legally appointed to be a substitute decision maker for the woman.

11. The cost of maintaining a brain dead pregnant woman in order to deliver a child is expensive, and availability and proper allocation of resources may be questioned. Public and private health insurance plans do not usually cover services after death is determined.

Recommendations

1. Women have the right to die in dignity. The goal of fetal rescue does not exonerate health care givers from the duty to respect this right of the primary patient, the woman.

2. Questions regarding maintaining pregnancy must be answered in consultation with the remaining family. In the absence of any expressed wish of the woman, her preference for the future of her fetus, to be kept alive or not, must be discussed. A substitute must act in the interests of the woman’s respectful treatment.

3. When brain-death occurs during pregnancy, whether or not to deliver the fetus must be decided in light of fetal viability. As long as the maternal condition is stable, all efforts should be made to prolong pregnancy and improve fetal maturity, provided proper fetal evaluation has ensured that no irremediable damage has occurred to the fetus at the time of maternal brain death. Appropriate surveillance of fetal well being should be implemented.

4. No mandatory lower gestational age limit should be set for the onset of fetal rescue after maternal brain death.

5. After maternal wishes and best interests are considered, the best interests of the fetus must also be considered, even where the fetus is in law not yet a person. Among the issues to be considered are: the
viability of the fetus and its probable health status before and after birth. All reasonable efforts should be made to promote the birth of an adequately mature, brain-intact neonate.

6. Allowing the fetus to die naturally in utero is appropriate if an irremediable maternal complication or acute fetal distress calls for an immediate delivery that carries the likely prospect of a severely compromised outcome. For the sake of a pregnant braindead woman and her fetus, it is advisable not always to strive to achieve conspicuous technical performance, nor always to try to wrest life from death.

Goa, March 2011

ETHICAL ASPECTS REGARDING CAESAREAN DELIVERY FOR NON-MEDICAL REASONS

1. The medical profession throughout the world has been concerned for many years at the increasing rate of Caesarean delivery. Many factors, medical, legal, psychological, social and financial have contributed to this increase. Efforts to reduce the excessive use of this procedure have been disappointing.

2. Caesarean section is a surgical intervention with potential hazards for both mother and child. It also uses more health care resources than normal vaginal delivery.

3. Physicians have a professional duty to do nothing that may harm their patients. They also have an ethical duty to society to allocate health care resources wisely to procedures and treatments for which there is clear evidence of a net benefit to health. Physicians are not obligated to perform an intervention for which there is no medical advantage.

4. Recently in some societies obstetricians have had increasing requests from women to be delivered by Caesarean section for personal rather than for medical reasons.

5. At present there is no hard evidence on the relative risks and benefits of term Caesarean delivery for non-medical reasons, as compared with vaginal delivery. However, available evidence suggests that
normal vaginal delivery is safer in the short and long term for both mother and child. Surgery on the uterus also has implications for later pregnancies and deliveries. In addition there is also a natural concern at introducing an artificial method of delivery in place of the natural process without medical justification.

6. Physicians have the responsibility to inform and counsel women in this matter. At present, because hard evidence of net benefit does not exist, performing Caesarean section for non-medical reasons is ethically not justified.

London, September 1998

ETHICAL GUIDELINES REGARDING INTERVENTIONS FOR FETAL WELL BEING

1. Most women will make choices to improve their chance of having a normal birth and healthy baby if they have access to the necessary information and support.

2. Extending care to the fetus by giving the pregnant woman the support she needs provides the best hope of enhancing the well-being of both the fetus and the mother-to-be.

3. Although the fetus may benefit from health care, it is completely dependent on the mother and any treatment must be through her body.

4. While the majority of women act in ways that provide a healthy environment and are usually ready to take risks on behalf of their fetuses, there may be situations where their interests do not coincide:
   a) the mother’s behaviour may create risks for herself and her fetus (for example, use of drugs, tobacco, and alcohol, not attending appropriately provided antenatal care, failure to take available HIV therapy.)
   b) the mother may choose not to accept diagnostic, medical or surgical procedures aimed at preserving fetal well-being, including Caesarean section for fetal indications.

5. The medical team has a responsibility to fully inform the mother, to
counsel her with empathy and patience, and to provide such support services as are needed to achieve the best maternal and fetal outcomes.

6. However, no woman who has the capacity to choose among health care options should be forced to undergo an unwished-for medical or surgical procedure in order to preserve the life or health of her fetus, as this would be a violation of her autonomy and fundamental human rights.

7. Resort to the courts or to judicial intervention when a woman has made an informed refusal of medical or surgical treatment is inappropriate and usually counter-productive.

8. If maternal capacity to choose for medical decision-making is impaired, health care providers should act in the best interests of the woman first and her fetus second. Information from the family and others may help to ascertain what she would have wished.

9. The wishes of pregnant minors who are competent to give informed consent regarding medical and surgical procedures should be respected.

Goa, March 2011 FIGO

**DEFINITION OF PREGNANCY**

Natural human reproduction is a process which involves the production of male and female gametes and their union at fertilisation. Pregnancy is that part of the process that commences with the implantation of the conceptus in a woman\(^1\), and ends with either the birth\(^2\) of an infant or an abortion\(^3\).

Cairo, March 1998

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1 Verification of this is usually only possible at the present time at 3 weeks or more after implantation.
2 WHO definition of a birth: 22 weeks’ menstrual age or more.
3 In some cases the dead products of conception may be reabsorbed or retained.
ETHICAL ISSUES IN THE MANAGEMENT OF THE SEVERE CONGENITAL ANOMALIES

Background

1. Human development is a complex process with exquisitely timed biochemical and biophysical differentiation, which occurs through embryonic and fetal life. Phenotypic structural and functional variations occur across the prenatal period. Most of these phenotypic variations are insignificant. In contrast, some can be severe which may result in either death or serious disability and these are termed severe congenital anomalies, which include serious malformations of the fetus.

2. Investigation and techniques used for prenatal diagnosis have advanced, resulting in increased detection rates of severe congenital anomalies. These methods include non-invasive and invasive diagnostic methods. The term “severe” is generally used to indicate malformations and/or anomalies that are potentially lethal or result in significant mental or physical disability.

3. Delivering and raising a severely malformed and disabled baby may have an impact on the physical, mental and social life of a family. Women should have the opportunity to consider an option of not continuing the pregnancy.

4. Cultural, social religious and personal beliefs may make termination of pregnancy not an option for that woman.

5. Legal regulations on termination of pregnancy differ among countries.

6. Although termination of pregnancy may be legally authorized in some countries for major congenital anomalies, there is no medical definition for the threshold of severity of fetal disease, nor is there a definition of a normal life for a neonate. Additionally, quantifying the risk of physical or mental abnormality leading to a serious handicap is a big challenge for healthcare professionals.
Recommendations

1. Women carrying a fetus with severe congenital anomalies or one at high risk for long term severe disability have the right to discuss and access a termination of pregnancy. The decision to continue or terminate the pregnancy should always rest with the woman.

2. Regardless of the legal availability of termination of pregnancy, there remains a responsibility to inform and counsel women about the risks and benefits of available fetal diagnostic testing, which may reveal severe congenital anomalies. As part of the counselling, a discussion of the benefits and harms of that knowledge should be done when options for management including termination are limited. If she agrees to carry out testing, her consent should clarify which details of information she would like to receive.

3. It is unethical and in many countries illegal to permit sex of the fetus to influence the decision to terminate a pregnancy.

4. In a situation of a multiple pregnancy, when one fetus has severe congenital anomalies, the decision for management of the pregnancy should always consider the well being of the normal fetus first.

5. Termination of pregnancy after 22 weeks should follow ethical guidance in “Ethical aspects of termination of pregnancy following prenatal diagnosis” (2007).

6. Following termination of pregnancy, consent should be obtained to confirm the fetal malformations and parents should be informed and counseled accordingly.

7. To assist the grieving process, parents should be offered the option of viewing the lost fetus as well as to perform the last rites as per their wishes.

8. In the event of a live birth of a fetus with a severe congenital abnormality, which is incompatible with life, appropriate palliative care should be offered. On the other hand if there is a live birth of a fetus with major congenital abnormality with a potential for survival, decisions should be based on expert advice about reasonable
treatment options that will not increase suffering and pain for the neonate.

London, March 2012

ETHICAL ASPECTS CONCERNING TERMINATION OF PREGNANCY FOLLOWING PRENATAL DIAGNOSIS

Background

1. Diversification and accuracy of investigational methods applied to prenatal diagnosis have considerably progressed during the past decade, leading to identify before birth of an increasing number of ill conditions known to severely affect the neonate. These methods include Pre-implantation Genetic Diagnosis (PGD), fetal DNA screening in maternal blood, chorionic villous sampling, serum biochemical screening tests for Down’s syndrome or neural tube defect, amniocentesis, cordocentesis. Diagnostic tools include molecular biology, such as Polymerase Chain Reaction (PCR), molecular genetics, Fluorescence In Situ Hybridisation (FISH) for rapid chromosomal defects detection, chromosomal micro satellite analysis, high definition fetal imaging with ultrasound, Doppler, MRI, helicoid scanner or fetoscopy.

2. In countries where these techniques are available, the main purpose of prenatal diagnosis is to inform parents of the presence of congenital diseases which may or may not lead to pre- or post-natal therapy or may lead to termination of pregnancy. Clearly PGD may avoid more difficult choices and, as appropriate, should be offered as an option.

3. Delivering and raising a severely malformed baby may create physical, mental and social harm to the parents and their other children. Some parents may choose to be informed to prepare for this burden. Others may find the burden will cause too great a harm. Denying parents the possibility to avoid the afflicting burden of a severely compromised child may be considered as unethical.

4. Cultural, religious or personal beliefs may compel women and
couples to oppose prenatal therapy or refuse medical abortion. For instance, Jehovah’s Witnesses may deny intra-uterine blood transfusion for their anaemic fetus. Similarly, strict religious obedience may allow termination of pregnancy only for reasons of maternal life-threatening conditions. In addition, invasive fetal investigations carry the risk of miscarriage, which may be unacceptable to the pregnant woman or couple.

5. Legal regulations on medical termination of pregnancy for fetal disease, if enacted, differ widely among countries. Some countries legally ban any termination of pregnancy, whatever the term of pregnancy and whatever the medical indication for abortion. Other countries legalise medical abortion up to the limit of “fetal viability”, usually 24 weeks, others accept termination of pregnancy for fetal disease up to full term.

6. Induced abortion practiced at mid-term and later has the potential of leading to the birth of a severely sick or malformed but live-born neonate. Provisions that ensure a stillbirth are usually practiced for fetuses undergoing a medical abortion beyond 22 weeks’ gestation.

7. In some countries, medical termination of pregnancy may be legally authorized only for a fetal disease which is of particular severity, incompatible with a normal life. There is no medical definition of the threshold of severity of a fetal disease, nor is there a social definition of a normal life for a neonate. Acceptability of a severely compromised life is highly dependant on the parent’s capacity to cope with the child’s condition.

8. Most of the time, termination of pregnancy is accepted for a proven fetal disease, i.e. irreparable congenital heart disease, gross brain malformation, which will later be eventually confirmed at autopsy. However, in some instances a medical abortion may be decided only because of a high risk, but not a certitude, of handicap or mental retardation, i.e. retinoid ingestion early in pregnancy, corpus callosum agenesis. In addition, chromosomal anomalies discovered at amniocentesis or brain malformations evidenced at routine ultrasound screening, and confirmed by MRI, may remain of unknown clinical consequence, and incite parents to request a termination of pregnancy. Due to the potential complexity of their
indications, no normative list of diseases deemed to justify medical abortion has been established, leaving the decision to each individual case.

9. In most countries where termination of pregnancy for fetal disease is accepted, prenatal diagnosis is directed to specialised multidisciplinary centres, including obstetricians, pediatricians, geneticists, pediatric surgeons, pathologists, and psychologists. When appropriate, medical termination of pregnancy is proposed, but never imposed, to patients. Patients are entitled to be fully informed of the condition of the fetus. The revelation of a fetal anomaly, whatever its severity, is always appalling for parents, who need not only technical advice, but above all full psychological and affective support. It is usually recommended that stillborn babies be presented to their parents, in order optimally to initiate the mourning and healing process.

10. Very premature neonates, as well as fetuses of the same gestational age, anatomically display nerve receptors to pain. Premature babies express reaction to pain and great attention is therefore paid to prevent or alleviate their suffering by appropriate precautions or medications. It is accepted that fetuses experience the same level of pain as neonates and that they respond to, and therefore are entitled to receive, the same type of medications. In addition, whenever a parent opts to maintain pregnancy for the severely affected or malformed fetus, all appropriate care, including pain relieving medication, is granted to the neonate as long as necessary.

Recommendations

1. Since it may offend personal, cultural or religious beliefs, no woman, beyond the practice of routine ultrasound screening, must be engaged in the process of prenatal diagnosis without being fully informed of its aims, including eventual termination of pregnancy, and its potential hazard of causing miscarriage.

2. In countries where it is an accepted medical practice, whenever a severe untreatable fetal disease or malformation incompatible with a normal life is diagnosed by prenatal diagnosis, termination of pregnancy must be offered to the parents. However, women and
couples must never be compelled to accept a medical abortion, whatever the severity of the fetal handicap, against their personal, cultural or religious beliefs. Parents must be fully informed of the condition of their fetuses. Physicians must not impose their personal preferences or beliefs, nor influence the decisions of parents placed in distress because of the diseases of their fetuses, and in a situation of high vulnerability.

3. Prenatal diagnosis and decisions to terminate pregnancy must be restricted to specialised, licensed, multidisciplinary centres subjected to regular quality controls. Parents seeking prenatal diagnosis must receive not only technical advice but also the benefit of full psychological support.

4. Termination of pregnancy following prenatal diagnosis must not be presented as an abortion, but as a pharmacologically-induced premature delivery, with full maternal pain relief and professional birth attendance, indicated only because the fetus, fully worthy of compassion, is affected by a severe untreatable disease or malformation.

5. When termination of pregnancy beyond 22 weeks is legal, most women and parents would prefer to deliver a stillborn in the circumstance of the fetus being affected by a severe congenital malformation. Offering counselling about the options designed to insure the delivery of a stillbirth is important.

6. Termination of pregnancy following prenatal diagnosis after 22 weeks must be preceded by a feticide starting with the injection into the fetal circulation of anesthetics and anti-pain medication. In order better to initiate the mourning process, parents must be encouraged, if they feel strong enough, to contemplate their stillborn babies after birth. If they would accept an autopsy, they must also be properly advised about its benefit in view of better counselling for a future pregnancy. The future child must never be presented as a substitute in replacement of the deceased fetus. Options for burial of the fetus must be offered to the parents according to their beliefs.
7. If after prenatal diagnosis parents opt to maintain pregnancy, appropriate care must be offered to their sick or malformed neonates.

*Lyon, June 2007*

**ANENCEPHALY AND ORGAN TRANSPLANTATION**

The FIGO Standing Committee on Ethical Aspects of Human Reproduction discussed aspects of anencephaly and organ donation for transplantation and made the following statement. There have been reports of the use of organs from anencephalic infants for transplantation. It is recognised that the ethical principles of beneficence and protection of the vulnerable can conflict. On the one hand, the principle of beneficence, the imperative of doing good, can apply to persons in need of organs. On the other hand, the principle of protection of the vulnerable newborn might apply in that an anencephalic infant might need protection against being treated only as a means to another’s advantage.

In view of the potential ethical issue, the following guidelines have been developed by the Committee.

1. The purpose of organ donation constitutes an ethical ground for a woman to choose to maintain an anencephalic pregnancy. Counselling of women and couples regarding organ donation should be undertaken by persons with no conflict of interest.

2. When an infant is born with signs of life but has no forebrain (anencephaly) and hence has no prospect of survival, with parental permission, the child may be placed on a ventilator for the purpose of organ donation following natural death. Any local legal definition of death is binding, but it may have to be reviewed in the light of scientific development of criteria of brain death in neonates.

*Lyon, June 2007*
SAFE MOTHERHOOD

Background

1. Maternity is a social function and not a disease. Societies have an obligation to protect women’s right to life when they go through the risky business of this social function that ensures the survival of our species. Maternal health care is not only important for avoiding maternal mortality and morbidity, but is also crucial for reducing the high burden of perinatal mortality and morbidity.

2. Worldwide, each year, about 287,000 women die – over 786 daily, exceeding one every two minutes – because of pregnancy and childbirth, an average maternal mortality ratio (MMR) of 251/100,000 live births. Of these deaths, 99% occur in resource poor countries. The woman’s lifetime risk of death due to pregnancy is 1/31 in Sub-Saharan Africa compared to 1/4300 in industrialised regions of the world.

3. Reduction of maternal mortality is one of the UN Millennium Development Goals; the goal set for MMR is 75% reduction by the year 2015. Without a concerted effort, this goal will not be achieved, especially in Sub-Saharan Africa and South Asia.

4. Hemorrhage is the leading cause of maternal death during pregnancy, accounting for more than one third of all casualties.

5. The majority of maternal deaths occur during labour. In most circumstances, pregnant women die because they deliver without the benefit of any skilled birth attendants.

6. The training of traditional birth attendants (TBAs) has proven to be inefficient on its own to reduce maternal mortality. The management of life-threatening complications in pregnancy and childbirth needs services which cannot normally be provided by TBAs.

7. Maternal deaths are nearly always related to three delays in implementing appropriate care: a delay in the recognition of life-threatening complications, a delay in transfer to a medical setting and a delay in access to proper obstetrical treatment.
8. The minimum rate of caesarean section to prevent avoidable maternal death is estimated to be around 5%. However, in countries with high maternal mortality, the rate of caesarean section is often less than 1%, due to a lack of health facilities and trained personnel.

9. Contributing factors to maternal mortality are early age at marriage, pregnancy occurring too early (before 18), too close (with less than two years intervals), too late (after 40), too frequently, illiteracy, malnutrition, lack of access to proper contraception and undue trust in the contraceptive value of breastfeeding.

10. About 180 million pregnancies occur each year. Half of these are unplanned, half of these unplanned pregnancies will end in induced abortion, 48% of which, around 22 million, are unsafe abortions, responsible for 70,000 annual deaths and 5 million disabilities, amounting to over 24% of all maternal deaths overall, but more in some countries. When countries have introduced legislation to permit abortion for non-medical reasons, the overall mortality and morbidity from the procedure has fallen dramatically, without any significant increase in the number of induced abortions.

Recommendations

1. Women’s mortality related to pregnancy remains unacceptably high, particularly in resource poor areas. Prevention of maternal death should be considered worldwide as a public health priority. Obstetric professional societies should publicise the tragedy of maternal mortality as a violation of women’s rights, and not just as a health problem. In advocating for safe motherhood as a human right, the health professions should collaborate with human rights advocates.

2. Since the main reason for maternal death is an avoidable delay in implementing proper emergency care during complicated labour, efforts should be made to provide all pregnant women with skilled birth attendants during delivery.

3. To achieve universal coverage of maternity services, obstetricians should play the role of team leaders, and delegate appropriate responsibility to other categories of trained and supervised health care providers.
4. Antenatal and intranatal care should be organised so that every woman with an obstetric life threatening complication would be transferred without delay to a medical centre providing the human and technical resources required for emergency obstetrical care, including caesarean section and blood transfusion.

5. Where abortion is not against the law, every woman should have the right, after appropriate counselling, to have access to medication or surgical abortion. The health care service has an obligation to provide such services as safely as possible. Proper medical and humane treatment should be made available to women who have undergone an unsafe abortion.

6. Family planning services and information should be made available for the timing and spacing of births.

7. The review of cases of maternal deaths should probe deeply into the underlying causes, beyond the clinical diagnosis.

8. Reduction of maternal mortality also depends on nonmedical policies such as development of suitable transportation means and roads accessible by vehicle and financial needs for underprivileged women, particularly within rural communities and in remote areas.

9. Obstetricians should lead the way in demonstrating how emergency obstetric care can be provided in a cost effective way in low resource settings. North to South and South to South collaborative efforts are needed to advance cost-effective strategies


London, March 2012 (updated)

ETHICAL GUIDELINES ON OBSTETRIC FISTULA

Background

1. Genital fistula in women is a distressing condition that can arise from
a number of causes. The most common and most devastating type of genital fistula in developing countries is obstetric fistula. Obstetric fistula is a preventable complication of labour that occurs when a woman endures prolonged obstructed labour without access to emergency operative delivery. In nearly all cases, her baby dies, and she is left with chronic urinary incontinence, less often fecal incontinence or both.

2. Once common throughout the world, obstetric fistula has been virtually eliminated in developed countries through improved obstetric care. However, today more than two million women are living with obstetric fistula in developing countries; approximately 50,000 to 100,000 new cases occur each year, mostly among young women and adolescents. These figures are likely to be gross underestimates as they are based only on the number of women seeking treatment. In developing countries where maternal mortality is high, fistula may occur at a rate of two to three cases per 1,000 pregnancies.

3. Several socio-cultural and health system factors contribute to the prevalence of obstetric fistula in developing countries. These include: lack of emergency obstetric care, young age at first pregnancy and labour, practice of severe forms of female genital mutilation, gender discrimination, poverty, malnutrition, and poor health service.

4. The medical, social and psychological consequences of untreated fistula are many. It can lead to frequent ulcerations, infections, damage to the nerves in the legs, kidney diseases, dehydration, depression, and even early death, including suicide. Women suffering from fistula are often abandoned by their husbands and family, or ostracized from their communities. Unfortunately, many women with fistula are either unaware that treatment is available, or the treatment is unaffordable.

5. These patients need not only medical care, but also social and psychological support and reintegration into the community.

6. The success rate of fistula repair by experienced surgeons can be as high as 90 per cent. After successful treatment, most women can resume full activities, although subsequent delivery should be by
Caesarean section. However, in most countries where obstetric fistula is prevalent, service is inadequate, inaccessible, or unaffordable for the majority of patients.

7. Programmes for the prevention of fistula will make a major contribution to the reduction of the ongoing tragedy of maternal mortality and morbidity.

Recommendations

1. Priority should be given to ensure access to adequate health care for all women during pregnancy and labour, and to provide emergency obstetric care for those women who develop complications during delivery.

2. The reduction of obstetric fistula requires the improvement of general health and girls’ nutrition, empowerment of women, the discouragement of early marriage, early childbirth, and high parity, and requires making family planning available to all who need it.

3. Appropriate strategies are needed for the eradication of female genital mutilation, which can be a cause of obstructed labour in many developing countries.

4. Until we succeed in eliminating obstetric fistula, priority should be given to building capacity for fistula repair by establishing specialised training and adequately equipped centers. In this regard, North to South and South to South cooperation is badly needed.

5. The management of obstetric fistula cases requires a coordinated team approach. Simple cases may be handled at district hospitals, while more difficult cases should be referred to specialised regional hospitals.

6. Prevention and treatment of obstetric fistula should be properly covered in the curriculum of reproductive health in the medical schools in developing countries. Postgraduate trainees should be involved in repair of obstetric fistula to gain the required surgical expertise in countries that are most affected.

7. Health education campaigns that target the communities under the
threat of obstetric fistula are badly needed. Strong messages that address its causes and ways of prevention should be prepared and tailored to suit different audiences in the target communities. Health care providers should make alliances among civil society, community and religious leaders to address the hidden and severe tragedy of obstetric fistula.

8. National obstetric and gynecology societies should encourage their governments to develop national strategies to eliminate obstetric fistula, with the help of partners of the Global Campaign for the Elimination of Fistula including the United Nations Population Fund, WHO and FIGO. As stated by WHO in the World Health Report 2005, “collective action can eliminate fistula and ensure that girls and women who suffer this devastating condition are treated so that they can live in dignity”.

London, March 2006

PREGNANCY AND HIV-POSITIVE PATIENTS

Background

1. Discrimination against individuals on grounds of their HIV-positive status violates their human rights. It is particularly important to the professional status and ethical conduct of healthcare providers that they should not participate, deliberately or by oversight, in this form of discrimination, or allow it by their staff members.

2. National courts of law and international human rights tribunals are increasingly active to condemn discrimination or disadvantage suffered by HIV-positive patients in receipt of, or their access to, services they require to maximize their health and maintain their capacity to function in their domestic, employment, social and related settings. Courts and tribunals are ruling that discriminatory attitudes and acts toward HIV-positive individuals disable them from enjoying rights available to others, and therefore make them disabled, even if they are asymptomatic.

3. A significant development in human rights law is through the U.N.
Convention on the Rights of Persons with Disabilities, which came into international legal effect on May 3rd, 2008. “Disability” is described as “an evolving concept…that…results from the interaction between persons with impairments and attitudinal and environmental barriers that hinders their full and effective participation in society on an equal basis with others.”

4. The Convention specifically recognises “that women and girls with disabilities are often at greater risk…of violence, injury, or abuse, neglect or negligent treatment, maltreatment or exploitation” than those not considered disabled.

5. Disabled women’s and girls’ vulnerability is aggravated by their pregnancy, and resulting dependency on gynecologists/obstetricians and related health service providers.

6. Article 23(1) of the Convention recognises disabled person’s rights “to found a family on the basis of free and full consent.” Article 25(a) concerns equal access to health care, “including in the area of sexual and reproductive health.” Article 25(d) requires that health professionals “provide care of the same quality to persons with disabilities as to others...by, inter alia...the promulgation of ethical standards for public and private health care.” Subsection (f) prohibits “discriminatory denial of healthcare or health services...on the basis of disability.”

7. Rights of pregnant patients disabled by HIV infection depend on discharge of the duties borne by agencies, facilities and personnel providing services to a general population not to discriminate against them. Facilities and personnel must be equipped to serve HIV infected pregnant patients. Provided that such patients have reasonable access to the services they need, it is not discriminatory that they receive care through specially equipped facilities, staffed by appropriately trained personnel. Similarly, a general facility’s referral of HIV-positive patients to such equipped facilities does not constitute discrimination against them.
Recommendations

1. HIV-positive patients must not be subjected to denial of care, or to inferior care, on account of their HIV status.

2. Practitioners must ensure that they and their staff members observe strict confidentiality of HIV-positive patients’ information and privacy, according to ethical standards and prevailing law.

3. Neither HIV testing nor pre- or post-test counselling should be required as a condition of women obtaining pregnancy testing, or prenatal, delivery, or post-partum care. HIV testing for purposes of healthcare should not be compulsory, nor imposed over patients’ refusal.

4. HIV testing should be offered routinely, but patients should be explicitly informed, and their choice to opt out should be respected. Whether testing is routine or offered as a voluntary choice, pre-test counselling, or at least information, should be offered. Post-test counselling should be offered, whether test results are positive or negative, but antiretroviral therapy should not be offered to pregnant patients whose HIV status is unknown.

5. Where specialised centers are established to provide appropriate care for HIV-positive patients, including prenatal, delivery and post-partum care and counselling, this should not be considered a form of discrimination against them.

6. HIV-positive women should not be discouraged from becoming pregnant. HIV treatment in pregnancy must extend into postnatal care, to avoid treating mothers solely as instruments to prevent HIV transmission to babies, as well as to promote mothers’ survival in their own right, and as caregivers to their children.

7. Practitioners should ensure that they and their staff members are familiar with the most recent clinical guidelines for care of their HIV-positive pregnant patients, and of their patients’ newborn children, relevant to the resources actually and potentially available to the practitioners and patients.

*Paris, October 2008*
PLANNED HOME BIRTH

Background

1. In many parts of the world, women have no choice but to deliver their children in their homes, with support only of the resources at hand. Against an often scantily provisioned background, a choice to plan for childbirth either in a hospital or comparably equipped birthing centre, or alternatively to deliver at home, appears an indulgence. When patients’ medical choices are available, they should be offered adequate information of the reasonably foreseeable risks, benefits, and implications of each option, from persons qualified to provide such information. The ethical goal of offering information is to serve women’s self-determination and human rights to respect.

2. In December 2010, a leading international human rights tribunal, the European Court of Human Rights, ruled that a law that interferes with physicians’ participation in women’s choice of planned home birth violates the women’s human rights. The tribunal found that pregnant women have a right to respect for their private and family life, which includes the right to choose to give birth at home. A law that deters physicians from providing professional assistance, by direct terms or ambiguity, obstructs women’s exercise of their right to choose their place of giving birth.

3. Arguments against the choice of home birth rely on a medical professional consensus that home birth is less safe than birth in a health care facility, and that a newborn child’s right to life and health includes safe birth. Records exist of home births attended by health professionals resulting in emergency hospital admissions, as well as of deaths or serious injuries to babies and/or mothers in home settings.

4. Counterclaims point to risks of hospital-borne infections, excessive, unwanted medical interventions, particularly unnecessary surgical deliveries, and the stress of being left alone due to limitations or prohibitions on the presence of partners and family members. Claims are made that it has not been proven that home births pose greater risks than births in hospitals. Further, it is asserted that decisions about risks to newborns and/or mothers are to be made by the mothers themselves, as aspects of their human right to self-
determination and their parental responsibility, rather than by legislatures, governmental regulators or medical professionals.

5. The European Court cited WHO recommendations in a 1996 report of a technical working group created by the Department of Reproductive Health and Research. Entitled Care in Normal Birth: a practical guide, the report notes that place of birth is an issue only in developed areas of countries, since in many parts of the world women have no choice but to give birth at home. The report also distinguishes high risk births, which should be managed in well staffed and equipped facilities, where they are accessible, from low-risk, normal births in which women have a choice between health facility and home delivery.

6. The report observes that, despite selective cases, there are generally inconclusive data on the relative safety of health facility and managed home births, but notes that women’s satisfaction tends to be higher in the latter. It reports that many factors deter women from choice of the former, including “the cost of a hospital delivery, unfamiliar practices, inappropriate staff attitudes, restrictions with regard to the attendance of family members at the time of delivery and the frequent need to obtain permission from other (usually male) family members before seeking institutional care.”

7. Properly attended home birth requires some essential preparations, including clean water, careful hand washing, a warm room and warm cloths or towels to wrap around the baby. There must also be at least some form of clean delivery kit as recommended by WHO, to create a clean site and give adequate treatment to the umbilical cord. The WHO report notes that “transport facilities to a referral centre must be available if needed,” but also recognizes obstacles in “parts of the world where fewer than 20% of women have access to any type of formal birth facility.”

8. The report presents a contradiction in that, in less developed parts of the world, women may have no access to the facilities or trained personnel they want to provide birthing care, whereas “[i]n a number of developed countries dissatisfaction with hospital care led small groups of women and caregivers to the practice of home births in an alternative setting.” Statistical data of outcomes were scarce at the
time it was written, but the report includes information from an Australian study that, in planned home deliveries, “the number of transfers to hospital and the rate of obstetric interventions was (sic) low. Perinatal mortality and neonatal morbidity figures were also relatively low, but data about preventable factors were not provided.”

9. The WHO report concludes that “a woman should give birth in a place she feels safe, and at the most peripheral level at which appropriate care is feasible and safe... For a low-risk pregnant woman this can be at home, at a small maternity clinic or birth centre in town or perhaps at the maternity unit of a larger hospital. However, it must be a place where all the attention and care are focused on her needs and safety, as close to home and her own culture as possible. If birth does take place at home...contingency plans for access to a properly-staffed referral centre should form part of the antenatal preparations.”

Recommendations

1. Where women have a choice to give birth in a healthcare facility or at home, healthcare providers should respect their right to prefer home birth. As with the choice of any patient, the patient should be informed about its risks and alternatives, and their implications. For instance, patients should be made aware that those at high risk of birth complications may not feel ill or show signs of distress, so that planning home birth should be carefully assessed.

2. Preparation for home birth should be as comprehensive as the circumstances allow, with clear and adequate contingency plans for transportation where feasible to a referral centre where properly trained and equipped services are accessible. A clean delivery kit as recommended by WHO should be made available.

3. Where the services of qualified obstetrician-gynecologists are not regularly available or requested, practitioners should collaborate to prepare midwives, nurses and/or other female caregivers, to support women approaching and in labour with their trained skills, emotional support and physical comfort, to reduce women’s anxiety. This should extend to preparation for labour, labour itself and postpartum
care of the mother and newborn(s) (see recommendations on Task-Shifting in Obstetric Care).

4. Where laws prohibit or prevent practitioners from providing assistance to women who propose home birth, practitioners and their professional societies should urge and collaborate in law reform to advance women’s human rights of choice, and to assure women of the best professional advice and care in making their decisions.

London, March 2012

TASK-SHIFTING IN OBSTETRIC CARE

Background

1. Maternal and newborn health constitutes a major health and development issue in low-resource settings. Every year, hundreds of thousands of women, living in low-resources settings, die from pregnancy- or childbirth-related complications.

2. Maternal mortality ratios (MMR) are high due to inadequacy of skilled healthcare personnel, poor access to healthcare facilities, and poor or no infrastructure, particularly in rural areas. For every maternal death, there are 20 women who suffer morbidity.

3. The most significant challenge to reducing maternal mortality in low-resource settings is the unavailability of specialists (obstetricians in low-resource settings).

4. The extreme shortage of obstetric specialists makes the safe management of labour an unrealistic option in low-resource settings. In response to this need, task-shifting has been promoted and used as a strategy to reduce maternal mortality globally.

5. The World Health Organization has described task-shifting as the rational redistribution of tasks among health workforce teams. When feasible, healthcare tasks are shifted from higher-trained health workers to less trained health workers in order to maximize the efficient use of health workforce resources.

6. The main types of human resources among whom tasks can be shifted
to accomplish safer deliveries are: Obstetricians, General Practitioners, Nurse Midwives, Nurses, and Trained Birth Assistants. The latter four types will be designed “mid-level providers” for the purposes of this document.

7. Due to unavailability of specialists in low-resource settings, mid-level health providers can provide obstetric care.

8. Task-shifting could include:
   a. Training of medical graduates (non-specialist doctors) for administration of general anesthesia, for ultrasound assessment, for instrumental deliveries, for cesarean section, for medical termination of pregnancy and other emergency obstetric care procedures.
   b. Training of nurses and midwives to extend their management skills in obstetric emergencies, such as use of misoprostol for postpartum hemorrhage (PPH), management of retained placenta, etc.
   c. Extending and upgrading the skills of those doctors who are already working in low-resource settings but are not fully skilled in emergency obstetric care.

9. Experience suggests that trained mid-level providers can significantly improve access to skilled emergency obstetric care, and manage life-threatening complications with referral where indicated.

10. Task-shifting can be a cost-effective method, and be a part of overall healthcare strategy, to reduce the burden on obstetric specialists in areas having high patient-to-specialist ratios. It also improves access to obstetric care in low-resource settings.

11. 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.

12. Developing a task-shifting strategy is a key component of effective obstetric care in low-resource settings. At present, there is a gap in evidence-based recommendations to guide policy and practice internationally.
Recommendations

1. Task-shifting should be a part of overall healthcare strategy in meeting the needs of pregnant women in low-resource settings. See the FIGO Safe Motherhood and Newborn Health Committee report Human Resources for Health in the Low-Resource World: Collaborative Practice and Task Shifting in Maternal and Neonatal Care.¹

2. General practitioners should be trained in basic elements of various skills in obstetrics, anesthesia, intensive care and neonatology, to provide comprehensive emergency care in low-resource settings. Where such providers are not available, mid-level providers need to be trained adequately, so as to provide basic stabilizing care with referral systems in place.

3. Implementation of a task-shifting strategy requires ongoing training, monitoring, and evaluation of the providers.

4. It is ethically preferable that obstetric specialists handle obstetric and neonatal emergencies. However, in situations where specialists are not available, it would be ethical to utilize services of trained mid-level providers.

5. It is important to ensure that efficient referral systems are in place to support increased access to emergency obstetric care. Hence, mid-level providers should be knowledgeable about available referral systems and how to use them.

6. The World Health Organization has defined key recommendations for the adoption of task-shifting as a public health initiative for global health. The Ethics Committee suggests that these recommendations serve as a template for considering task-shifting in obstetric care, along with the FIGO report in 1 above.

London, 2012

ETHICAL GUIDELINES ON CORD BLOOD BANKING

Background

1. Cord blood contains blood stem cells, which are useful in transplantation for patients with a range of malignant and hematological conditions (leukemias). There is a low incidence of Graft v Host reaction, and of viral disease transmission.

2. The time at which the cord is cut after delivery of the infant has important consequences for his/her health. Early cord clamping may decrease the infusion of cord blood to the neonate, with the potential for decreased blood volume or anemia. Late cord clamping may result in increased blood volume that contributes to hyperbilirubinemia, which, although not harmful to the baby, may cause distress to the family. Cord clamping therefore requires individualization, for the benefit of the individual neonate.

3. Current policies have focused on the standards for collecting and storing cord blood (and other tissues), but not on the impact of collecting cord blood on neonatal outcomes or the provision of maternal services. In addition, payment of physicians, nurses or other caregivers to collect cord blood creates a conflict of interest between choices they make to serve the best interests of neonates and mothers, and financial rewards they may earn for themselves by collection.

4. Some prospective parents are approached by commercial cord blood banks and encouraged to purchase storage of their children’s cord blood for hypothetical self-use in case of future progress in regenerative medicine. This likelihood is presently exceedingly low. Furthermore, there are no guarantees of the commercial continuation of these companies, or the successful storage of viable stem cells should they be needed for transplantation.

5. There are multiple concerns about autonomy of decision-making for parents regarding cord blood banking. Generally, mothers-to-be are asked to give consent to cord blood recovery and banking during pregnancy, when the well-being of their future children is their
primary concern. Information is often biased towards the potential but unlikely benefit for the developing child. In particular, stressing the potential use for a future child of HLA-matched blood is considered exceptional. Parents may also experience significant peer pressure from other parents to agree to banking if the marketing is pervasive and compelling.

6. The storage of cord blood in the public or mixed public/private health system is considered of benefit to society at large, enabling broader availability of stem cell transplantation. This raises the question of whether this resource, if found to be valuable, is best organized primarily as a private venture for those with the means to purchase services, or more broadly as a publicly funded service that would allow individuals’ access on the basis of their needs, regardless of their financial means.

7. Storage of cord blood may also expand the availability of rare HLA groups for the purpose of transplantation.

Recommendations

1. Obstetricians or midwives who are asked to collect cord blood have a primary duty to ensure safe outcomes for the women and their children. This takes priority over any other endeavour, such as meeting a contract made prior to delivery for cord blood collection.

2. As in all other cases, appropriate and non-coercive consent and counseling of a mother-to-be (and her partner if feasible) depend on accurate information.

3. If practitioners decline to undertake cord blood collection due to pressure of workload in their units, they may recommend other units where collection is routinely practiced under safe conditions.

4. Early cord clamping for the purpose of collecting cord blood should not be done if there is a risk of childhood anemia.

5. Ideally, cord blood banking should be organised at a national or other public level, with a publicly accountable body that can collect and
store the samples appropriately, and in a manner that reflects the demographic composition of the population.

London, March 2012

ETHICAL GUIDELINES ON RESUSCITATION OF NEWBORNS

Background

1. According to the UN Convention on the Rights of the Child, all children from birth have a right to life, and are protected against discrimination of any kind, irrespective of their parents’ or legal guardians’ race, sex, colour, language, religion, political or other opinion, national, ethnic or social origin, property, disability, birth or other status. Internationally accepted human rights instruments include the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. It is essential to consider the welfare of individual children within the context of respect for their human rights, since there are reported cases of improper discrimination against the newborn on the grounds of sex, colour, disability or ethnicity.

3. There are uncertainties in many cases about both the chance of survival of the newborn, and the risk of permanent disability. Furthermore, the wide variability of outcomes of delivery, based on local factors, adds to this uncertainty.

4. There is a huge disparity in the availability of means of care for newborns between resource-poor and resource-rich regions and individual hospitals.

5. Availability and quality of ante-natal care have a major influence on the child’s condition at birth and on the long-term outcome. Consistent management plans, before and after birth, may improve this outcome. Conflicts and disputes between obstetricians, pediatricians, and other health professionals can cause distress and confusion for parents, and compromise effective care.

6. Since the interests of parents and of other members of the family are
inextricably intertwined with those of the newborn, the parents have the right both to be informed of the child’s diagnosis and prognosis and to be involved in the decision-making process.

7. Outcome studies consistently demonstrate that the survival of extremely preterm infants is improved in those transferred to large centres before delivery.

8. Survival and outcome of extremely preterm neonates are critically dependent on gestational age and birth weight. Long-term follow up studies of extremely preterm infants have demonstrated a substantial incidence of neurological, cognitive and behavioural problems in survivors. However, in published studies, the majority of adolescent and adult survivors have assessed their quality of life favourably.

9. Furthermore, obstetric and neonatal care are continuing to evolve and improve at a rapid pace. Hence by their very nature, long-term outcome studies measure outcomes following a standard of care that may have become outdated.

10. There is evidence that the provision of sensitive and empathic support, at the time of and immediately following the death of an infant, has long-term positive consequences for the psychological well being of the parents and family.

Recommendations

1. Newborn infants should be treated with the consideration and respect due to any other human being. As the most vulnerable members of society, they have a right to be cared for before, during and immediately after birth.

2. Decisions on management should be based on what is perceived by the parents and their medical advisors as in the child’s best interests, uninfluenced by the child’s gender or by religious, demographic or financial factors. If they disagree, independent adjudication should be sought.

3. The most experienced clinicians available at the time (preferably a consultant obstetrician and a consultant pediatrician with an experienced midwife), should agree a provisional management plan,
based on clinical information and up-to-date outcome data. If possible, time should be allowed for all concerned to consider the options and assimilate the information.

4. The doctor counselling parents should be careful not to impose his or her own cultural or religious convictions on those whose beliefs may be different, bearing in mind the legal requirements of the country and ethical duties regarding any conscientious objection.

5. When the burdens and risks of resuscitation and invasive treatment exceed the likely benefits to the individual child, it is in the child’s best interests to not initiate, or to withdraw, any attempt at resuscitation.

6. When there is uncertainty as to whether a particular infant may benefit from intensive care, it may be appropriate to institute “provisional” intensive care until the clinical progress of the infant, and consultation between an experienced member of staff and the parents, clarify whether it is better to continue or withdraw intensive care.

7. Medical staff have an ethical responsibility to keep parents informed about the likely clinical outcome resulting from the decisions about clinical management. Doctors should be aware of relevant data on outcome according to gestational age, and of audited data from their own centre.

8. The doctor counselling the withholding or withdrawal of medical treatment should be the most experienced available. When appropriate, the doctor may wish to consult with colleagues or with an ethics Committee. The doctor should discuss the problem and the management plan with other members of the healthcare team, including the nursing staff.

9. When the parents do not agree with each other, or when they do not accept their doctor’s advice, as to whether or not to withhold intensive care, such treatment should be pursued until a change in the baby’s status or further counselling and discussion clarifies the situation. Only as a last resort, in exceptional circumstances, and after all other options have been exhausted, may the case be referred to a court of law.
10. When a decision has been taken to withhold life-sustaining treatment, all conversations with the parents, the reasons, as well as the clinical course of the child, should be promptly and carefully documented in the child’s record.

11. Infants from whom life-sustaining support is withheld or withdrawn should receive, when necessary, analgesia and symptom control medication and continue to be kept warm, offered nourishment, and treated with continued attention, dignity and love. All efforts should be made to ensure that parents can be with them as much as possible, should they so wish.

12. After death following the withholding or withdrawal of medical treatment, the medical team has an ethical responsibility to request parental consent for a necropsy examination, in order to confirm and complete the diagnosis, with a view to further counselling the parents and advising them on the outlook for future pregnancies.

13. Member societies and neonatal societies should advise governments of the importance of establishing integrated perinatal centres, together with regional organisation of perinatal care. The importance of these centres in reducing mortality and morbidity should be highlighted. Continued professional training of all personnel involved in resuscitation and immediate neonatal care is mandatory.

14. Member societies and neonatal societies should encourage close monitoring and record-keeping of perinatal care, and maintain records of all births and their outcome on a regional basis.

15. In this respect, North to South and South to South collaborations in all aspects of neonatal care are necessary, and should be encouraged.

London, March 2006

ETHICAL ASPECTS OF THE MANAGEMENT OF SEVERELY MALFORMED NEWBORN INFANTS

1. The Committee recognised that newborn infants with severe malformations have the right to be allowed to die with dignity, without inappropriate or futile medical intervention when it is the
considered view of both the parents and their doctors that this course is in the child’s best interest.

2. The qualification “severe” is used in this context to indicate malformations that are either potentially lethal or whose nature is such that even with medical treatment they are likely, in the view of the parents and their medical advisers, to result in unacceptable mental and/or physical disability.

3. The Committee considered active euthanasia to be ethically unacceptable even when it appeared to be in the best interest of the child. However, the withholding or withdrawal of medical care (for example artificial ventilation, antibiotics, naso-gastric feeding, supplemental oxygen) is justified in such circumstances, provided that comfort care, including the offer of oral feeds, warmth, love and respect are maintained. The use of analgesics and sedative drugs to relieve distress and suffering is considered appropriate provided that their primary aim is not to cause death.

4. The individual decision to withhold or withdraw medical care should be made in the interest of the child, and should not be determined by matters such as the sex of the infant or by eugenic, demographic or financial factors.

5. Prior to discussing the possibility of withholding or withdrawing medical care, the medical team has a responsibility to fully investigate and document the status of the malformed infant and to counsel the parents on their baby’s condition, prognosis and on the management options.

6. However, when a malformed infant fails to breathe at birth, it is ethically acceptable to withhold resuscitative measures when the anomaly is of a severity that precludes doubt as to the wisdom of prolonging life. When doubt exists, resuscitation should be undertaken and medical care given until further investigation and consultation with the parents and colleagues has been sought.

7. Usually, the doctor counselling the withholding or withdrawal of medical care should be the most senior available. When appropriate, the doctor may wish to consult with colleagues or with an ethics Committee. The doctor should discuss the problem and intended
actions with other members of the health care team, including the nursing staff.

8. In counselling parents, the doctor should be careful not to impose his or her own cultural and religious prejudices on those whose beliefs and practices may be different, bearing in mind the legal requirements of the country. When a doctor’s beliefs prevent the disclosing of all the possible options to the parents, the doctor has a duty to refer them to a colleague who is able to do so.

9. In discussing their problem, parents should be encouraged to seek advice from others. When appropriate, they should be positively encouraged to seek further professional advice. They should always be given the opportunity of speaking together in private before reaching a decision.

10. The doctor counselling parents may not necessarily be seeking an outright decision, but rather may be trying as sensitively as possible to gain insight into their wishes and hence to spare them avoidable distress and feelings of guilt.

11. When there are two parents, but they do not agree with each other as to whether or not to withhold or withdraw care, medical treatment should be pursued until the situation clarifies itself, either because of changes in the baby’s status or as a result of further counselling and discussion. Only as a last resort, in exceptional circumstances and after all other options have been exhausted, should the problem be referred to the law courts.

12. When a decision has been taken to withhold or withdraw life-sustaining care, all actions taken and the reasons for them, as well as the clinical course of the child, should be carefully documented.

13. After death following the withholding or withdrawal of medical care, the medical team has an ethical responsibility to request parental consent for a necropsy examination in order to confirm and complete the diagnosis, with a view to further counselling the parents and advising them on the outlook of future pregnancies.

Jerusalem, 1995
ETHICAL ASPECTS CONCERNING NEONATAL SCREENING

Background

Screening procedures in the neonatal period can be divided into those that are part of routine screening for all newborn babies, either by clinical examination or biochemical tests, and those procedures for conditions such as hearing loss, congenital heart disease, congenital cataracts, and cryptorchism, congenital dislocation of the hip, and other congenital malformations that will require separate testing.

The aim of newborn screening (NBS) is to detect newborns with serious, treatable disorders to facilitate appropriate interventions to avoid or ameliorate adverse outcomes. The condition sought should be an important health problem, and there should be an accepted treatment for patients with recognised disease as well as availability of facilities for diagnosis and treatment. The condition to be screened must be severe, frequent and amenable to easy, safe, reliable and inexpensive laboratory diagnosis on a very large scale.

All developed countries have instituted NBS programmes, while developing countries have been slow to implement NBS, and most have not yet started. Two recent advances have greatly accelerated the pace of NBS development: modification of tandem mass spectrometry and DNA extraction and analysis. New directions of NBS will depend on the development of effective treatments for hitherto untreatable disorders and advancing technology. The technical ability to perform a screening procedure does not guarantee its ethical acceptability. Susceptibility testing has been considered, but it remains unethical unless there is a clearly beneficial intervention available in childhood.

The principle of autonomy embodies the right of parents to have informed choice about screening procedures, but on the other hand, WHO considers that NBS “should be mandatory and free of charge if early diagnosis and treatment will benefit the newborn”.

Along with the pediatrician, the obstetrician is involved in the education of parents regarding the availability of NBS tests, the benefits of early detection, the risks that exist for infants who do not receive screening, the process of screening and follow-up, and government requirements that
may exist. Consent practices in NBS programmes are poorly described and probably vary markedly. NBS programmes are ethically acceptable when they are evidence-based, take into account the opportunity cost of the programme, distribute the costs and benefits of the programme fairly, and respect human rights.

Recommendations

1. The benefit-to-harm ratio must be favourable whenever a screening programme is being put forward for implementation.

2. All screening examinations should be preliminary, and involve further investigation to verify that those who screen positive really do have the abnormality and require treatment, and to eliminate those who screen positive but do not actually have the abnormality. Potential harm exists with false-positive results as well as in false negative cases.

3. The obstetrician and the gynecologist must be knowledgeable about the sensitivity and specificity of screening tests, adequate follow up testing, and appropriate counselling for parental consultation regarding both positive and negative results.

4. NBS programmes have an obligation to be informative about sample retention and to have policies that prohibit any use of an identified sample after completion of the screening tests without written permission from parents. Specific consent for sample retention for research must be subject to separate consent related to the long-term uses and implications of research.

5. Despite the principle of autonomy, which considers the right of parents to have informed choice about screening procedures, in view of the fact that the overall acceptability of NBS is beyond doubt, NBS should be mandatory and free of charge if early diagnosis and treatment will benefit the newborn. It is an obligation for health professionals to make information on NBS programmes available to parents.

6. Obstetricians and gynecologists should contribute to the assessment of their national and local disease burden, making sure that the prevention and care of genetic and congenital conditions are not neglected, and are given an appropriate place among other health
priorities. Failure to provide NBS results in avoidable harm, breaching the principle of non-maleficence and the principle of distributive justice.

Paris, October 2008

ISSUES IN CONTRACEPTION AND ABORTION

FEMALE CONTRACEPTIVE STERILISATION

Background

1. Human rights include the right of individuals to control and decide on matters of their own sexuality and reproductive health, free from coercion, discrimination, and violence. This includes the right to decide whether and when to have children, and the means to exercise this right.

2. Surgical sterilisation is a widely used method of contraception. An ethical requirement is that performance be preceded by the patient's informed and freely given consent, obtained in compliance with the Guidelines Regarding Informed Consent (2007) and on Confidentiality (2005). Information for consent includes, for instance: that sterilisation should be considered irreversible; that alternatives exist such as reversible forms of family planning; that life circumstances may change, causing a person later to regret consenting to sterilisation; and that procedures have a very low but significant failure rate.

3. Methods of sterilisation generally include tubal ligation or other methods of tubal occlusion. Hysterectomy is inappropriate solely for sterilisation because of disproportionate risks and costs.

4. Once an informed choice has been freely made, barriers to surgical sterilisation should be minimized. In particular: sterilisation should be made available to any person of adult age; no minimum or maximum number of children may be used as a criterion for access; a partner's consent must not be required, although patients should be encouraged to include their partners in counselling; and physicians
whose beliefs oppose participation in sterilisation should comply with the Ethical Guidelines on Conscientious Objection (2005).

5. Evidence exists, including by governmental admission and apology, of a long history of forced and otherwise non-consensual sterilisation of women, including Roma women in Europe and women with disabilities. Reports have documented the coerced sterilisation of women living with HIV/AIDS in Africa and Latin America. Fears remain that ethnic and racial minority, HIV-positive, low-income, and drug-using women; women with disabilities; and other vulnerable women around the world are still being sterilised without their own freely given, adequately informed consent.

6. Medical practitioners must recognise that, under human rights provisions and their own professional codes of conduct, it is unethical and in violation of human rights for them to perform procedures for prevention of future pregnancy on women who have not freely requested such procedures or who have not previously given their free and informed consent. This is so even if such procedures are recommended as being in the women’s own health interests.

7. Only women themselves can give ethically valid consent to their own sterilisation. Family members – including husbands, parents, legal guardians, medical practitioners and, for instance, government or other public officers – cannot consent on any woman’s or girl’s behalf.

8. Women's consent to sterilisation should not be made a condition of access to medical care – such as HIV/AIDS treatment, natural or cesarean delivery, or abortion – or of any benefit such as medical insurance, social assistance, employment, or release from an institution. In addition, consent to sterilisation should not be requested when women may be vulnerable, such as when requesting termination of pregnancy, going into labor, or in the aftermath of delivery.

9. Further, it is unethical for medical practitioners to perform sterilisation procedures within a government programme or strategy that does not include voluntary consent to sterilisation.

10. Sterilisation for prevention of future pregnancy cannot be ethically
justified on grounds of medical emergency. Even if a future pregnancy may endanger a woman's life or health, she will not become pregnant immediately, and therefore must be given the time and support she needs to consider her choice. Her informed decision must be respected, even if it is considered liable to be harmful to her health.

11. As for all non-emergency medical procedures, women should be adequately informed of the risks and benefits of any proposed procedure and of its alternatives. It must be explained that sterilisation must be considered a permanent, irreversible procedure that prevents future pregnancy and that non-permanent alternative treatments exist. It must also be emphasized that sterilisation does not provide protection from sexually transmitted infections. Women must be advised about and offered follow-up examinations and care after any procedure they accept.

12. All information must be provided in language, both spoken and written, that the women understand, and in an accessible format such as sign language, Braille, and plain non-technical language appropriate to the individual woman's needs. The physician performing sterilisation has the responsibility of ensuring that the patient has been properly counseled regarding the risks and benefits of the procedure and its alternatives.

13. The UN Convention on the Rights of Persons with Disabilities includes recognition “that women and girls with disabilities are often at greater risk...of violence, injury or abuse, neglect or negligent treatment, maltreatment or exploitation.” Accordingly, Article 23(1) imposes the duty “to eliminate discrimination against persons with disabilities in all matters relating to marriage, family, parenthood and relationships, on an equal basis with others, so as to ensure that:

a) The right of all persons with disabilities who are of marriageable age to marry and to found a family...is recognised;

(b) The rights...to decide freely and responsibly on the number and spacing of their children...are recognised, and the means necessary to enable them to exercise these rights are provided;

(c) Persons with disabilities, including children, retain their fertility on an equal basis with others.”
Recommendations

1. No woman may be sterilised without her own previously given informed consent, with no coercion, pressure, or undue inducement by healthcare providers or institutions.

2. Women considering sterilisation must be given information of their options in the language in which they communicate and understand, through translation if necessary, in an accessible format and plain non-technical language appropriate to the individual woman's needs. Women should also be provided with information on non-permanent options for contraception. Misconceptions about prevention of sexually transmitted diseases (STDs), including HIV, by sterilisation need to be addressed with appropriate counselling about STDs.

3. Sterilisation for prevention of future pregnancy is not an emergency procedure. It does not justify departure from the general principles of free and informed consent. Therefore, the needs of each woman must be accommodated, including being given the time and support she needs – while not under pressure, in pain, or dependent on medical care – to consider the explanation she has received of what permanent sterilisation entails and to make her choice known.

4. Consent to sterilisation must not be made a condition of receipt of any other medical care – such as HIV/AIDS treatment, assistance in natural or cesarean delivery, or medical termination of pregnancy – or of any benefit such as employment, release from an institution, public or private medical insurance, or social assistance.

5. Forced sterilisation constitutes an act of violence, whether committed by individual practitioners or under institutional or governmental policies. Healthcare providers have an ethical response in accordance with the guideline on Violence Against Women (2007).

6. It is ethically inappropriate for healthcare providers to initiate judicial proceedings for sterilisation of their patients, or to be witnesses in such proceedings inconsistently with Article 23(1) of the Convention on the Rights of Persons with Disabilities.

7. At a public policy level, the medical profession has a duty to be a voice of reason and compassion, pointing out when legislative,
regulatory, or legal measures interfere with personal choice and appropriate medical care.

*Goa, March 2011*

**ETHICAL ISSUES IN THE MANAGEMENT OF SEVERELY DISABLED WOMEN WITH GYNECOLOGICAL PROBLEMS**

**Background**

1. When severely physically or mentally disabled female children and adolescents mature, several concerns arise, from menstrual hygiene to their vulnerability to sexual abuse, unwanted pregnancy and sexually transmitted diseases including HIV.

2. One must distinguish the vulnerabilities of severely physically disabled women from severely mentally disabled women. The former are usually able to decide on their health care and treatment in the same way as other women although not able to protect themselves physically, but the latter may not be able to make decisions for themselves. They may therefore need a substitute for decision-making in their best hygienic and health interests. If a proposed substitute decision-maker appears affected by a conflict of interest, a practitioner will have to apply independent judgment of the disabled woman’s best interests. In any event, the disabled woman should be involved in the decision to the full extent of her capacity.

3. Severely disabled women who may menstruate may also enjoy an active sexual life, and procreate just as other women do, taking into account the welfare of any future children they may have and their ability to look after them.

4. In order to prevent pregnancy in both severely physically and mentally disabled women, permanent sterilisations have been carried out. This has included women who meet the criteria for independent, autonomous decision-making and consent. If they were to be sterilised without their voluntary consent, this would be unethical and a violation of their human rights. See the FIGO recommendations on Female Contraceptive Sterilisation, 2011.
5. There are reports of women with severe disability receiving surgical and medical treatments to induce amenorrhea, including irreversible and higher risk surgical approaches such as hysterectomy, without appropriate consent. For such cases, see the FIGO recommendations on Female Contraceptive Sterilisation, above.

6. In contrast to involuntary permanent contraception and sterilisation, which are conducted without the subjects’ true consent and considered human rights violations, there are contexts where non-voluntary procedures may be considered, such as the very rare cases in which women are so severely mentally disabled as to be unable to express or even comprehend their choices. In many jurisdictions, the women’s legal guardians may ask the courts to allow such procedures as being in the women’s best medical and psychological interests. After considering medical and related evidence, if the court agrees, it is then considered ethical as well as legal to conduct judicially approved procedures.

Recommendations

1. It is essential that the general hygienic and other health needs of women with severe disabilities be managed without discrimination, by current standards of care and management applicable to all women.

2. Healthcare providers should advocate policies that prohibit discrimination on the basis of physical and/or mental disability, and that guarantee equal legal protection to all.

3. If a woman has no capacity to decide on meeting her hygienic and other health care needs, decisions must be made in her best interests by her substitute decision-maker(s).

4. Procedures that unavoidably result in permanent sterility or termination of pregnancy require special consideration to ensure comprehension, capacity to choose, and consideration of the issues with severely disabled women’s consent, or, when their wishes cannot be determined, that of other appropriate decision-makers including court appointed guardians if needed.

5. If a woman is too mentally disabled to comprehend menstruation,
and evidence shows that each month the experience severely upsets her, or she is not able to maintain personal hygiene during menstruation, it is both ethically and medically prudent to recommend the least invasive and appropriate medical or surgical options.

London, March 2012

ETHICAL CONSIDERATIONS RESPECTING THE USE OF ANTI-PROGESTINS

1. The Committee agrees that individuals have the right to enjoy the benefits of new scientific knowledge.

2. An anti-progestin drug has been marketed as a safe and effective method for the medical termination of pregnancy. However, its introduction has been associated with widespread controversy.

3. In countries where anti-progestins have been made available, there is no evidence to suggest that they have increased resort to induced abortion. The method simply provides women with a choice between medical and surgical termination of pregnancy.

4. Unsafe abortion of an unwanted pregnancy has been estimated to be responsible for the death of a woman every three minutes throughout the world. Many more will suffer from serious morbidity. Society has an obligation to tackle this serious public health problem. Together with other methods, anti-progestins may help to address this problem.

5. It is recognised that in the future anti-progestins are likely to offer other therapeutic uses unrelated to pregnancy termination. This research should be encouraged.

1994
1. The principle of beneficence requires that new contraceptive methods must be safe, effective, and acceptable to women.

2. In introducing new contraceptive methods, medical practitioners must be guided by respect for an individual’s autonomy. This respect for autonomy is reflected in international standards of reproductive rights.

3. The same respect for autonomy requires that standards especially relevant to the introduction of new methods of fertility regulation should both facilitate informed choice, and deliver quality care.

Informed choice

4. Informed choice is a process by which a woman can freely make decisions about possible health interventions and places decision-making in women’s hands so that they can exercise their rights. The foundation of informed choice is information that is “accurate, unbiased, complete and comprehensible”.

5. Respect for informed choice requires that certain information on contraceptive methods should be provided to every woman considering using them, including:
   - proper use
   - contra-indications
   - effectiveness in preventing pregnancy
   - continuing to protect against sexually transmitted infections
   - possible side-effects
   - possible interaction with other drugs or conditions.

6. Respect for women’s autonomy requires that each woman should be explicitly informed that at any time she can decide to stop using the method she chooses (for example she should be able to have an intrauterine device or implantable contraceptive removed on request).

7. Healthcare practitioners are ethically required to work to eliminate obstacles to informed choice. To that end, among other efforts, power imbalances must be acknowledged and minimised. Staff must be well
trained; alternative methods of conveying information must be in place in order to respond to women who, for instance, cannot read; staff biases and objections to methods of fertility regulation must not be conveyed to patients.

Quality of care

8. The duty to benefit patients requires that an important goal of practitioners should be to offer contraceptive methods within the context of high quality reproductive and sexual health services. There are two major aspects to this: medical quality requirements, and the need to take into account women’s expressed wishes. Firstly, medical quality requirements include that a range of appropriate contraceptive methods is offered, that appropriate supportive counselling services are available, and that providers are technically competent. The second aspect requires that interpersonal relations with healthcare personnel be respectful and take into account women’s input and opinions.

Ljubljana, 1996

ETHICAL ASPECTS OF INDUCED ABORTION FOR NON-MEDICAL REASONS

1. Induced abortion may be defined as the termination of pregnancy using drugs or surgical intervention after implantation and before the conceptus has become independently viable (WHO definition of a birth: 22 weeks’ menstrual age or more.)

2. Abortion is very widely considered to be ethically justified when undertaken for medical reasons to protect the life or health of the mother in cases of molar or ectopic pregnancies and malignant disease. Most people would also consider it to be justified in cases of incest or rape, when the conceptus is severely malformed, or when the mother’s life is threatened by other serious disease.

3. The use of abortion for other social reasons remains very controversial because of the ethical dilemmas it presents to both women and the medical team. Women frequently agonise over their difficult choice, making what they regard in the circumstances to be the least worse decision. Health care providers wrestle with the moral values of preserving life, of providing care to women and of avoiding unsafe abortions.

4. In those countries where it has been measured, it has been found that half of all pregnancies are unintended and that half of these pregnancies end in induced termination. These are matters of grave concern, in particular to the medical profession.

5. Abortions for non-medical reasons, when properly performed, particularly during the first trimester when the vast majority take place, are in fact safer than term deliveries.

6. However, the World Health Organization has estimated that nearly half the 40 million or more induced abortions performed around the world each year are unsafe because they are undertaken by unskilled persons and/or in an unsuitable environment.

7. The mortality following unsafe abortion is estimated to be very many times greater than when the procedure is performed in a medical environment. At least an estimated 75,000 women die unnecessarily each year after unsafe abortion and very many more suffer life-long ill-health and disability, including sterility.  

8. Unsafe abortion has been widely practiced since time immemorial. Today it occurs mainly in countries with restrictive legislation with respect to the termination of pregnancy for non-medical reasons. Countries with poorly developed health services and where women are denied the right to control their fertility also have higher rates of unsafe abortion.

9. When countries have introduced legislation to permit abortion for non-medical reasons, the overall mortality and morbidity from the

procedure has fallen dramatically, without any significant increase in terminations.

10. In the past, most pregnancy terminations were undertaken surgically, but recent pharmaceutical developments have made it possible to bring about safe medical abortion in early pregnancy.

11. In addition, the reproductive process can be interrupted before pregnancy begins by classical contraceptive methods or by the more recently popularised emergency contraception. The latter is not an abortifacient because it has its effect prior to the earliest time of implantation. Nevertheless, these procedures may not be acceptable to some people.

Recommendations

1. Governments and other concerned organizations should make every effort to improve women’s rights, status, and health, and should try to prevent unintended pregnancies by education (including on sexual matters), by counselling, by making available reliable information and services on family planning, and by developing more effective contraceptive methods. Abortion should never be promoted as a method of family planning.

2. Women have the right to make a choice on whether or not to reproduce, and should therefore have access to legal, safe, effective, acceptable and affordable methods of contraception.

3. Provided that process of properly informed consent has been carried out, a woman’s right to autonomy, combined with the need to prevent unsafe abortion, justifies the provision of safe abortion.

4. Most people, including physicians, prefer to avoid termination of pregnancy, and it is with regret that they may judge it to be the best course, given a woman’s circumstances. Some doctors feel that abortion is not permissible whatever the circumstances. Respect for their autonomy means that no doctor (or other member of the medical team) should be expected to advise or perform an abortion against his or her personal conviction. Their careers should not be prejudiced as a result. Such a doctor, however, has an obligation to
refer the woman to a colleague who is not in principle opposed to inducing termination.

5. Neither society, nor members of the health care team responsible for counselling women, have the right to impose their religious or cultural convictions regarding abortion on those whose attitudes are different. Counselling should include objective information.

6. Very careful counselling is required for minors. When competent to give informed consent, their wishes should be respected. When they are not considered competent, the advice of the parents or guardians and when appropriate the courts, should be considered before determining management.

7. The termination of pregnancy for non-medical reasons is best provided by the health care service on a non-profit-making basis. Post-abortion counselling on fertility control should always be provided.

8. In summary, the Committee recommends that after appropriate counselling, a woman has the right to have access to medical or surgical induced abortion, and that the health care service has an obligation to provide such services as safely as possible.

Cairo, March 1998

GUIDELINES IN EMERGENCY CONTRACEPTION

Background

1. The Committee recognises that basic human rights to health include the freedom to control sexual and reproductive health. Individuals also have the right to enjoy the benefits of new scientific knowledge in sexual and reproductive health.

2. The Committee noted in its statement on The Role of the Ob/Gyn as an Advocate for Women’s Health that “Failure to advocate policies that will improve women’s health care and advance women’s rights broadly will deleteriously influence the health care of the individual patient cared for by the ob/gyn”.

133
3. In unprotected intercourse, emergency contraception is highly effective in diminishing the number of unwanted pregnancies without the need of an abortion. (See above, Definition of Pregnancy) Early evidence suggests that abortion rates among teenagers drop following access to information and use of emergency contraception.

Recommendations

1. Early access to hormonal emergency contraception improves the success rate of prevention of pregnancy and therefore decreases health risks. Therefore, at a public policy level, the medical profession should advocate that emergency contraception be easily available and accessible at all times to all women.

2. Emergency contraception is not medically appropriate as an ongoing contraceptive method. Physicians have the obligation to ensure accurate information is available regarding emergency contraception, as well as to discuss future strategies for individuals to avoid the need for emergency contraception.

3. Access to emergency contraception should be an essential component of immediate care for women who suffer rape and are exposed to the risk of pregnancy. Adolescents, because of their special vulnerability in society, form another group for whom emergency contraception should be made easily available.

London, June 2001

ETHICS IN FAMILY PLANNING

Background

1. Family planning enables couples and individuals to decide freely and responsibly on the number and spacing of their children, to have the information and means to do so, to ensure informed choices, and have available a full range of safe and effective methods.

2. Although tremendous advances have been made in the development of safer and more effective contraceptives and in the provision of affordable and accessible family planning services, millions of
individuals and couples around the world are still unable to plan their families as they wish.

3. In some countries, there are social and economic incentives and disincentives that affect individual decisions about child-bearing and family size, in order to lower or raise fertility.

4. Different cultures, religions, societies and communities as well as different political and economic situations in countries have resulted in different positions on methods of fertility regulation, and views are changing with time. Views are affected by the legal disposition of governments to provide fully available, informed choices to couples or individuals to practise family planning.

5. The modern revolution in contraceptive methods has provided women with reliable methods of family planning, which they can use independently or in cooperation with their male partners. However, with many contraceptive methods, women have to assume the inconvenience and the risk involved.

Recommendations

1. The obstetrical and gynecological professions and other relevant health workers should enable and support responsible voluntary decisions about child-bearing and use of methods of family planning of individual’s choice, as well as ensure availability of methods for regulation of fertility that are not against the law. Professional associations must play a pivotal role in ensuring the availability of contraceptive services and ongoing research in this area.

2. In no case should abortion be promoted as a method of family planning. Prevention of unwanted pregnancies must always be given the highest priority, and all attempts should be made to eliminate the need for abortion. In circumstances in which abortion is not against the law, such abortion should be safe. Where abortion law is restrictive and a heavy burden of unsafe abortion is evident, practitioners and associations should urge wider legal access to services.

3. Legal or social coercion about the type or timing of family planning should be avoided. as this violates ethical principles as well as human
rights. Obstetricians and gynecologists should act as advocates for appropriate and safe methods of family planning.

4. Males should share the responsibility in family planning, but it should be noted that in reproductive health there is a heavy burden on women. The importance of male participation and responsibility in the protection of women has become much greater with the emergence of HIV/AIDS.

5. If a physician or health worker is either unable or unwilling to provide a desired method of family planning or medical service for non-medical reasons, he or she should make every effort to achieve appropriate referral.

Paris, October 2008

ISSUES IN ADVERTISING AND MARKETING HEALTH SERVICES

ETHICAL BACKGROUND FOR ADVERTISING AND MARKETING

The dissemination of accurate information to the public regarding advances in knowledge, medication, procedures and expertise is essential for patients to make the best informed choice regarding their treatment. Ensuring accuracy of information is an obligation of the profession, since ensuring patient trust is the foundation of the therapeutic physician/patient relationship.

Health authorities, medical institutions, media, and physicians must provide accurate information to ensure a high standard of health for the population. Information that unduly accentuates benefits over harms is unethical, and the use of information for advertising to promote the practice of physicians or institutions in order to increase financial returns is equally unethical, irrespective of the quality of the information.

2003
GUIDELINES FOR PHYSICIAN RELATIONSHIPS WITH INDUSTRY

Background

There are legitimate ties between physicians and drug and device manufacturers. There are potential conflicts of interest, however, between the industry, regarding promotion of their financial gain and the physician’s duty to benefit patients. Physicians act de facto as promoters and distributors of the products of industry. Promotion pressure from industry representative or through direct marketing to patients may lead to overprescribing or overuse by the physician of drugs or testing devices/equipment.

Recommendations

1. Physicians should be associated only with treatments that have been peer reviewed or that have been investigated under careful appropriate methodology.

2. The physician must avoid any conflict of interest through ownership of medical facilities, stock in companies or other roles in industry that would influence the use of any pharmaceutical device or procedure for treatment of patients in their care.

3. Gifts, meals and other promotions can create a conflict of interest for physicians. Expensive gifts, whether related to a particular product or of general utility, should not be accepted by members of the medical and allied professions.

4. Use of gifts that advertise specific products should be avoided in the office of a physician.

5. Appearances of physicians, at events, lectures and the like specifically to promote drugs or devices is ethically questionable, even when the conflict of interest is revealed. The temptation to bias the presentation (for example by including only positive study results, or excluding an adequate explication of alternative therapies) to benefit the company paying presenters, is real. Physicians should not accept
such lectureships or appearances if they are unable to give a full and unbiased presentation.

6. Physicians have the fiduciary responsibility to their patients of continually reviewing their own direct and indirect financial conflicts of interest to ensure they are not influenced in the prescribing of drugs, devices or other appliances.

7. Attempts by industry to control prescriptive practices of physicians, either by avoiding generic medications or the use of codes, should be rejected by physicians as not in the best interest of their patients. Physicians should not enter into agreements with pharmacies or other suppliers regarding filling prescriptions written by code.

8. Physicians should not direct patients to consultation, tests, prescriptions or treatments that are not necessary for their management but are proposed for the physicians’ personal financial benefit.

2003

RECOMMENDATIONS FOR MEDICAL INFORMATION AND ADVERTISING ON THE WEB

Background

An enormous body of medical information, with the potential for enhancing patient and health professional education, exists on the World Wide Web. Any patient can access this database. Some of the information will be pertinent to the patient’s interests and validated through publication in peer review journals or validation by national oversight of clinical trials, etc. Some of the information will be frankly promotional in nature, with information that is not validated by recognised scientific methods and even at times intentionally deceptive, claiming results that have never been proven in order to sell a specific product. Identification of the quality of the research and efforts to interpret the information in light of prior information forms a critical filter for patients and others seeking to obtain information through this vehicle. General awareness of the lack of such oversight for medical information on the web is limited,
and often the fact that something is written implies a validity or success that is not supportable.

Institutions such as the press, political parties, religious groups, cultural associations, and industrial or financial lobbies may attempt to spread medical information of a biased nature or non-validated information, in order to support their own views, interests, beliefs, propaganda or philosophy. In addition, influential medical authorities may share these views and provide endorsement for these points of view even though the evidence and quality of research are lacking. These inherent biases are not identified, and the reader’s ability to identify the fact that this is in reality lobbying for a point of view rather than sharing medical facts in an unbiased fashion may be limited. Patients need to be able to discriminate between lobbying, which is meant for the initiating group’s benefit, and information that is designed for the sake of public education.

Similarly, advertising on the web is focused on personal or institutional benefit. Hospitals, health institutions and professional practice groups are entitled to promote services and describe services available. However, the quality of those services and the limits of availability of services are rarely critically identified, again leading to a biased and potentially harmful choice by patients if they should seek care that is not available or of questionable quality based on this advertising approach. Veracity of claims in this venue requires the same level of adherence to ensuring adequate credentials and availability of services as for all other medical services in order to prevent harm to patients.

**Recommendations**

1. Since claims on the web may convey inaccurate medical information, it is recommended that physicians provide cautions to their patients in interpreting these data. Alternative sites for patients to visit that are validated through peer review, controlled and well-designed clinical trials, or national or professional oversight to ensure that bias is eliminated, are important to identify for patients choosing this venue for their education.

2. Advertising for health systems, individual and group physician practices, and for other health services is increasing on the web. Oversight of the validity of the claims made by entities in order to
attract business is limited to nonexistent. Education or guidelines for patients about assessment of scientific validity of claims, as well as the inherent bias of advertising for profit, does fall within the peer view of physicians as a means of ensuring that their and other patients are not harmed in the course of seeking care or seeking health information.

3. Advertising health benefits or harms that support a particular political or religious agenda without balancing this view is inherently harmful to patients and to the general health of the population. Creating an understanding of the role of bias in presentation of health information for political or religious promotion is part of a physician’s duty to ensure that patients benefit from health care information.

2003

ETHICAL ISSUES IN MEDICAL EDUCATION

ETHICAL ISSUES IN MEDICAL EDUCATION: GIFTS AND OBLIGATIONS

One of the founding documents of the professional codes taken by multiple generations of medical students, the Hippocratic Oath, recognises the inherent responsibility of trainees to respect their teachers. It does not, however, make clear the enduring responsibility that all health professionals carry to teach, because they themselves have received the gift of education.

The time, financial resources – both personal and institutional – and talent that are invested in each individual, generate a reciprocal obligation to the public to ensure that the next generation of professionals, as well as the public, receives a thorough education. Furthermore, given the unique issues represented by women’s health, and the limited access to trained health professionals and current professional education for women worldwide, there is an enhanced obligation to pass on the scarce resource this education represents.

However, the obligations of educators and learners have boundaries that
must be appreciated to ensure that the unequal relationship of those with knowledge and power (educators) and those with need (learners) is not exploited.

There are also responsibilities that both educators and learners have towards patients involved in medical education. The benefits and burdens of medical education have direct impacts on individual patients. There are clear benefits to society at large as well as to individual patients from the increased oversight and review characteristic to teaching settings.

However, the burden of interactions such as student history and physical examinations, the potential for prolonged procedures in the learning curve, and the intrusion of multiple health providers and learners into an individual’s personal space and privacy are significant.

These guidelines are intended to clarify the professional obligations between patients, learners and educators in the setting of medical education.

Recommendations

1. It is incumbent on physicians to strive to improve their skills and knowledge. Physicians also have an obligation to share their skills and knowledge with colleagues, by the provision of education; both formal and by example.

2. Teachers have a duty to ensure that learners are functioning with patients only at levels appropriate to their training.

3. The imbalance of power between students and teachers requires careful boundaries that prevent exploitation. Retribution, humiliation or fear have no place in the learning environment. Great care should be taken to ensure that no expectation of personal service, reward, or relationship, including sexual relationships, be allowed in this teaching setting. Furthermore, students should be assured of receiving due credit for their work, particularly in a research setting.

4. The close nature of the student/teacher relationship in medical education and mentoring is critical to support the growing independence of the learner and support patient safety. While there is
a professional student/teacher relationship, no sexual or romantic relationship is appropriate.

5. Students have significant obligations to both patients and teachers. These include a responsibility to professional ethics of honesty, confidentiality, and respect for both the patient and the teacher.

6. Although the importance of medical education is widely recognised, people should never be coerced into being part of the educational process, although it is appropriate to explain to them the benefits of education for the general enhancement of health care standards.

7. Women, worldwide, are disadvantaged by a power differential between men and women in society. This places an additional obligation on teachers and learners to ensure that the burdens of medical education do not fall disproportionately on women as a class, and to ensure that women are given a full opportunity to consent to or refuse the inclusion of learners in their health care. This includes circumstances where learning might occur when the patient is fully anesthetized.

8. Ethnicity, socioeconomic status or a person’s identification as part of a specific group should never be used in a discriminatory fashion as a basis for selection as a teaching patient.

*Luxor, November 2005*

**GUIDELINES ON ETHICAL ISSUES INVOLVED IN ADVERTISING OF CREDENTIALS AND EDUCATION**

**Background**

Accurate identification of individual credentials and qualifications provides important guidelines for patients seeking the right physician for their illnesses. It is also critical for physicians looking for appropriate referral sources, since their own credibility as well as the best care for their patients rests on accurate information about training. Medical institutions such as hospitals and practice groups, professional organizations and councils all have an obligation to be sure that standards of credential verification are set and that abuses are publicly reported. The trust that the
public places in their health care professionals, as well as the quality of their health care and the potential for harm from care delivered by an unqualified health professional, require physicians to take an active role in ensuring the accuracy of advertised credentials and education.

Guidelines

1. Office signs, business cards and print announcements should be limited to credentials issued only by nationally or internationally recognised credentialing bodies.

2. National medical councils should maintain registries of updated credentials of physicians that may be used as a reference for physicians and then as needed by patients or others.

3. Procedures should exist nationally and in appropriate organisations for investigation of allegations of false advertisement. The appropriate medical authority should impose measures in respect of any physician who is proved to have committed false advertisement.

4. A specific review board should be established in the different organisations of mass media to audit contents of medical articles, programmes and interviews before they are published or broadcast in the mass media. Because of the impact of false information on public health, the medical media and the individual physician have an ethical responsibility to ensure that any advertised credentials or experience are accurate.

5. To avoid conflicts of interest and enlighten the public, the media should clearly indicate whether a health professional or drug or device manufacturer has paid for presentation of an article, commentary, or interview. This allows the public to evaluate whether the material is potentially biased and make decisions based on this evaluation, whether the material is an independent news item or an advertisement. It is the responsibility of all researchers and physicians to report new diagnostic and therapeutic modalities and their success rates in peer reviewed journals so the process of peer review can ensure the quality and value of the research results. This must be done prior to any dissemination in the mass media, and the
results of peer review evaluations of the research should be clearly indicated when it is advertised in mass media.

2003