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

OCTOBER 2015
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*These statements are the result of research and discussion between the FIGO Committee for the Ethical Aspects of Human Reproduction and Women’s Health and the FIGO Committee for Women’s Sexual & Reproductive Rights.*

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FOREWORD

Obstetrics and gynecology, dealing with all of human life’s major transitions—conception, birth, reproduction, aging, and death—has seen the greatest medical advances create ethical challenges for practitioners. Ethical challenges range from public advocacy for meeting the basic needs of health and human rights of women to the most intricate issues raised by evolving knowledge and use of the human genome.

In 1985, FIGO established its Committee for the Study of Ethics in Human Reproduction and Women’s Health (the Ethics Committee) with the main objectives to record and study general ethical concerns in research and practice in women’s health, and bring these to the attention of practitioners, policy-makers and the wider public in economically developed and developing countries. From its inception, the Ethics Committee has made recommendations for guidance of and stimulation of discussion among all practitioners, and particularly for use by Member Societies to promote broader national and regional discussion of challenging ethical issues.

All of the recommendations are available on the FIGO website, www.figo.org, in English, Spanish and French, for publication, translation and circulation, provided only that due acknowledgement is given to their origins in the FIGO Committee for the Study of Ethics in Human Reproduction and Women’s Health. Subject to such acknowledgement, there is no copyright restriction on their use or citation.

Bernard M. Dickens, 2015.

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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.
A. GENERAL ISSUES IN WOMEN’S HEALTH AND ADVOCACY

THE ROLE OF THE OB/GYN AS AN ADVOCATE FOR WOMEN’S HEALTH

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

ETHICAL ISSUES AFTER SEXUAL ASSAULT

Background

1. Sexual assault is a crime of violence against a person’s body and will or intent. A 2013 WHO report on sexual violence against women describes sexual assault as “…the use of physical or other force to obtain or attempt sexual penetration. It includes rape, defined as the physically forced or otherwise coerced penetration of the vulva or anus with a penis, or other body part, or object, although the legal definition of rape may vary…” [1]. For instance, in some jurisdictions, husbands are not convictable of rape of their wives, although they may still be convicted of assault, which includes sexual assault.

2. Sex offenders use physical and/or psychological aggression or coercion to victimize, often threatening the victim’s sense of privacy, autonomy or self-determination, and well-being. Sexual assault can cause physical trauma and significant psychological anguish and suffering. Persons of
any sexual disposition or orientation are liable to suffer sexual assault, but women are the overwhelming majority of victims.

3. The incidence of sexual assault of women is difficult to assess accurately, since for personal, cultural or, for instance, protective reasons women may prefer not to disclose sexual assaults committed against them, whether by strangers or family members. For instance, wives may suppress evidence lest bread-winning assaultive husbands be imprisoned or otherwise removed from the home. Social stigmatization of assaulted women may also deter them from making reports. Nevertheless, extensive empirical and anecdotal evidence shows that sexual assault against women, of all ages, social groups, and social standing is widespread, and that prompt acquisition of forensic evidence for purposes of law enforcement is necessary.

4. Forensic examinations provide evidence of sexual assaults, and facilitate identification, prosecution, conviction, and punishment of offenders. Examinations are for purposes of law enforcement, although they are usually followed by arrangements to meet women’s needs of appropriate medical care.

5. Forensic testing ranges from noninvasive examinations such as of clothing and underclothing, urine tests, and blood sampling, to more intrusive examinations such as vaginal or rectal examination.

6. A balance must be struck between acquiring forensic evidence, including internal examinations for recovery of assailants’ tissues and diagnoses of sexually transmitted infections, and women’s needs for supportive care. Forceful or insensitive conduct of a forensic internal examination has been criticized as amounting to “the second rape.”

7. A comprehensive 2013 US protocol for medical forensic examinations provides that “Acute medical needs take precedence over evidentiary needs. Patients should be instructed not to wash, change clothes, urinate, defecate, smoke, drink, or eat until initially evaluated by examiners, unless necessary for treating acute medical injuries. If... patients need to urinate prior to the arrival of examiners, ensure that the urine sample is collected properly while maintaining the chain of custody” [2].
8. In some regions, unmarried women complaining of rape were subjected to what is usually known as “the two finger test,” to determine their prior sexual activity. This is now recognized to be unscientific, subjective, and of no forensic value, and itself a violation of women’s rights to privacy, physical and mental integrity, and dignity.

9. Law enforcement, including the gathering of forensic evidence to achieve this goal, is primarily a responsibility of government. Governments have interests to ensure that trained, sensitized personnel are available, and adequately equipped, to examine and provide care to women disclosing sexual assaults, on a priority, emergency basis. The time that women spend awaiting examination, for instance through transportation delay and distance from examination sites, may cause loss of critical evidence, and unduly aggravate women’s trauma.

10. Consent is required for medical forensic examination of women who have suffered sexual assault. Women or guardians of women unable to give consent themselves need to understand that this examination is for purposes of law enforcement, but that following the examination women’s health needs and concerns will be fully addressed. For adolescents’ and younger victims’ consent, see the FIGO statement and recommendations on “Adolescent and youth reproductive health care and confidentiality.”

11. Contracting a sexually transmitted infection (STI) from an assailant, such as HIV infection, is typically a significant concern in the care of women who have suffered sexual assault; see FIGO statement and recommendations on “Ethical aspects of HIV infection and reproduction.” However, such testing is an individual decision for each woman. A positive test result may lead to appropriate care, but its appearance in the woman’s medical record may present disadvantages. She should be adequately informed of the advantages and disadvantages before deciding whether or not to pursue testing.

12. Sexual assault that may cause pregnancy requires additional testing after the initial examination. Postcoital contraception can reduce the risk of pregnancy after assault. Women of different ages, social, cultural, and religious or spiritual backgrounds may differ on treatment options they find acceptable.
13. In addition to training in forensic science, examiners require training in forensic law, including court and judicial processes, in order to not be intimidated when presenting forensic evidence in court and being cross-examined. A concern is that women who have suffered sexual assault may prefer necessary examinations to be conducted by trained women, but due to sexist prejudice, courts and lawyers may fail to give trained women’s testimony due weight.

Recommendations

1. Women disclosing a recent sexual assault should have access to rapid evaluation and examination, be treated for serious injuries, and offered a medical forensic examination. They may be traumatized, so sensitized care for gathering evidence should be provided. If specialized rape crisis centers are unavailable, private locations should be provided for women’s intake and rest awaiting examination, and for those accompanying them, such as family members.

2. Consent is required for conduct of medical forensic examinations including tests. Necessary information provided to the women or their guardians, while respecting their free choice, should stress advantages of this examination, including validation of the assault, possible identification of assailants from tissue samples, and potential protection of other women and girls against further assaults.

3. Women’s pelvic examination by “the two finger test” is discredited, and where not legally prohibited should be abandoned and prevented.

4. Women should be informed that failure to consent to medical forensic examination may prevent collection of evidence that would assist their legal recourse and appropriate care. Any reasons given for refusal of consent to specific examinations should be documented.

5. Consent should be requested from minors if they are sufficiently mature to decide, but otherwise from their parents or other guardians.

6. Women should be offered appropriate medical and mental health care, whether or not they consent to specific or any medical forensic examinations.
7. Women’s risk of contracting any STI or HIV from the assault is typically a significant concern for them. Testing should be determined on an individual basis in consultation with each woman. Treatment and preventive care should be offered, which, on women’s consent, may be given before the results of diagnostic tests are available. Provision of prescriptions is especially valuable when assaulted women are unlikely to return for further care after their initial visits.

8. Unwanted pregnancy is another risk of sexual assault that women of reproductive capacity usually take seriously, including those using routine contraception. If forensic examinations are conducted within the time period for emergency contraception, this treatment should be explained, and afforded to women with their consent, but otherwise they should be referred for clinical care options (see FIGO recommendations on “Healthcare professionals’ responses to violence against women”). Forensic examination personnel who have religious or other objections to advising, prescribing, or administering emergency contraception or other indicated treatment should comply with FIGO “Ethical guidelines on conscientious objection” to ensure immediate care of patients who request this treatment.

9. On confidentiality of women who have been assaulted and mandatory reporting, see Recommendation 8 of the FIGO statement on “Healthcare professionals’ responses to violence against women.”

10. Every gynecologist who is responsible for conducting medical forensic examinations should be trained, equipped, and willing to present evidence in court. This is an ethical duty toward sexually abused women, of all ages, that professionalism requires be discharged.

London, March 2014

Reference

ETHICAL GUIDANCE ON HEALTHCARE PROFESSIONALS’ RESPONSES TO VIOLENCE AGAINST WOMEN

Background

1. The UN defines violence against women as “any act of gender-based violence that results in, or is likely to result in, physical, sexual or mental harm or suffering to women, including threats of such acts, coercion or arbitrary deprivation of liberty, whether occurring in public or private life” [1]. This may also include verbal violence such as insults, threats or shouted commands or condemnation.

2. The range of violent conduct that women experience should not be underestimated, because its effects are not always directly physical. Emotional injury may induce clinical depression or anxiety, or lead to substance abuse and comparable forms of self-harm, including attempted suicide.

3. A comprehensive WHO study reported that 35.6% of all women worldwide will suffer physical or sexual violence in their lifetime, usually from a male partner [2]. The WHO Director-General observed that such reports show that violence against women is a global health problem of epidemic proportions, as a matter both of public health and clinical care. Violence against women is found everywhere, not particular to any national, geographical, racial, ethnic, religious, or socioeconomic group. It is a violent offence against women’s health, and against women’s human rights.

4. In addition to risks of violence that women face from their domestic or intimate partners, vulnerable or socially marginalized women are at increased risk. Sources of risks vary, for instance assailants exploiting positions of authority, and assaults during social turmoil, military conflict, and other conditions of lawlessness. This may occur in the context of governmental and/or community indifference. Evidence shows violence against women to be a strategic instrument in intercommunal or armed strife, and to occur widely for instance in refugee camps, including by “peacekeeping” forces.

5. Sexual violence against women has special relevance to gynecologists and obstetricians. It can lead to unintended pregnancy, and its
termination, whether by safe and legal means or by unsafe means, when
women are or feel isolated. Women’s termination of pregnancy is more
likely to present health risks when it is illegal. Sexual violence can also
lead to other gynecological problems, such as direct injury to the
reproductive tract, or sexually transmitted infections including HIV.
Violence during pregnancy increases the likelihood of spontaneous
abortion, stillbirth, preterm delivery, and the birth of low birth-weight
babies.

6. The 2013 WHO clinical and policy guidelines highlight “the critical
role that the health system and health-care providers can play in terms
of identification, assessment, treatment, crisis intervention,
documentation, referral, and follow-up” [3]. The guidelines observe
that “although violence against women has been accepted as a critical
public health and critical care issue, it is still not included in the health-
care policies of many countries,” and appears “poorly understood or
accepted within national health programs and policies” [3]. The
guidelines further point to deficiencies in healthcare professional
education that leave providers ill-equipped to deal effectively with
patients victimized by domestic, stranger-initiated, or other violence.

7. Despite providers’ commonly inadequate preparation for case
management, evidence shows that women who have experienced
violence are more likely than nonabused women to seek health care.
Healthcare providers are often the first contacts for survivors of
violence and sexual assault. Assaulted women often identify healthcare
providers as the professionals they most trust with disclosure of such
abuse. Gynecologists may be preferred because they may examine
patients in privacy, in the absence of, for instance, husbands or
mothers-in-law. They therefore have a responsibility to equip
themselves to respond to patients’ needs, and to keep confidentiality.

8. Patients may not be immediately forthcoming about violence they have
experienced. Thus, gynecologists and their staff members may
encounter more women victims of violence than they realize. However,
the 2013 WHO guidelines [3] observe that “universal screening” or
“routine enquiry” should not be implemented, meaning that women
should not be asked in all healthcare encounters about their exposure
to violence or sexual assault as routine, but that judgment should be
exercised in each case.
9. Jurisdictions vary on whether reporting of violence against women is mandatory, on which care-givers are obliged to report, and to which agencies reports must be submitted. Even where reporting is not legally compelled, however, involved nongovernmental organizations and international human rights agencies consider it necessary that such violence be documented, to link suspected offenders to injuries, and to facilitate interventions and support advocacy on behalf of victims.

Recommendations

1. Member societies of FIGO should support the prequalification and postqualification training of all relevant healthcare providers, particularly gynecologists, obstetricians, midwives, and nurses, in identification of women who have experienced intimate partner or other violence and sexual assault. This may be through direct training programs, continuing professional education, or university-based or comparable courses, modelled, for instance, on the 2013 WHO guidelines [3] and other authoritative guidance.

2. Training should address the eliciting and diagnosis of the type of violence, including when and how to enquire about a patient’s history or threat of suffering violence, and how to collect forensic evidence if required in the doctor–patient setting. Training should also include a basic knowledge about violence, including relevant laws, available community and other support for victims, and (in)appropriate attitudes among healthcare providers.

3. When women disclose violence, healthcare professionals should assess their conditions, asking questions when necessary to improve the diagnosis and the women’s immediate and subsequent care. Clinical care should be woman-centered, with clinicians offering support that includes consultation in private with maximum confidentiality, being nonjudgmental, and validating patients’ narratives through careful, respectful listening. Enquiries about their experience of violence should not pressure women to talk, be guarded when interpreters are involved, aim to increase safety for patients and their children when needed, and help patients to access available resources.

4. Care for victims should, as far as possible, be integrated into existing services rather than stand as separate services in order to avoid...
stigmatization and improve access, with health systems giving priority
to service delivery at the primary care level, to assure broad access to
knowledgeable care. Healthcare providers unable to offer first-line
support should promptly refer women to accessible alternative sources.

5. Women presenting shortly after sexual assault should be offered
appropriate protection against sexually transmitted infections and
emergency contraception. If presenting later or emergency
contraception fails, women should be offered abortion services in
accordance with applicable law. Care options for patients pregnant at
the time of assault should be discussed with them, and administered in
conformity with their choices.

6. Personnel who have religious or other objections to advising,
prescribing, administering, or participating in indicated treatment
should comply with FIGO Ethical Guidelines on Conscientious
Objection to ensure timely treatment on patients’ requests.

7. Providers should also consider and set up longer-term care, provide
emotional support, and refer patients to relevant information and
available services, such as for depression, post-traumatic stress disorder,
anxiety, substance addiction, and unexplained chronic pain. Responses
to patients’ concerns should not intrude on patients’ autonomy, but
provide choices for help and self-help. Plans for follow-up care should
be discussed with patients to monitor their conditions and
interventions that the providers and/or other care-givers have
administered.

8. Laws mandating reporting evidence of violence have to be followed,
but otherwise providers should not report incidents or conditions of
violence as a matter of routine. They should discuss with their patients
the implications of mandatory reporting, and options of voluntary
reporting, for instance to agencies able to offer protection or relief.
They should ensure their patients’ awareness of their rights, and follow
their preferences on disclosure.

9. If laws that mandate reporting are considered harmful, providers
should advocate their reconsideration or refinement.

London, March 2014
References


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 post conception. 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: See also Recommendations A1 (The role of the ob/gyn as an advocate for women’s health 1999) and A 14 (Ethical guidelines on conscientious objection).

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); the International Convention on the Elimination of All Forms of Discrimination Against Women (1979); and the International Convention on the Rights of the Child (1989). Sexual and Reproductive Human Rights have also been identified by the International Conference on Population and Development, in Cairo (1994), and reaffirmed by the Fourth World Conference on Women, in Beijing (1995), and the UNESCO Declaration on Bioethics and Human Rights (article 6) 2005.

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 militate 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 ISSUES IN TREATING FAMILY MEMBERS AND CLOSE FRIENDS

Family members and close friends may ethically be given advice, but actively treated only in exceptional, temporary circumstances. Challenges to confidentiality arise from dual responsibilities of acting as medical professionals and family members.
Background

1. Family members and close friends of physicians commonly want to discuss healthcare issues with them, and ask for advice, for themselves or others close to them. Some may go further, and ask for treatment, prescriptions or other services such as referrals that physicians are professionally able and entitled to provide. They may have more trust and confidence in physicians they know than in strangers.

2. Similarly, physicians sometimes suggest to family or household members and friends how their general health may be promoted, and offer advice and assistance within their medical specialty, devoted to the well-being of those for whose welfare they are particularly concerned. In providing advice or care to family members or close friends, however, there is a potential for subjective evaluation rather than the objective appraisal necessary in a professional relationship.

3. Physicians’ provision of general advice concerning minor ailments to family members and friends, whether requested or volunteered, and ordinary minor (“band aid”) treatment that could be provided by a parent or family member who is not a licensed healthcare provider, are generally ethically not problematic. In the case of potentially more serious conditions, however, this may confuse the distinction between physicians’ personal and their professional relationships, and introduce a potential for conflict of interest and subjectivity. Therapeutic treatment is acceptable only in emergency, until recipients are transferred to independent care. The same restraint governs physicians’ self-medication.

4. Concerns are especially acute for gynecologists, since intimate questioning, disclosures and/or physical examinations of care recipients may be medically required for appropriate diagnosis and care that practitioners are socially inhibited from conducting. Similarly, recipients of care may not be aware of the necessity of such questioning and examinations, especially concerning contraceptive and other sexual practices. They may also be inhibited from seeking second opinions.

5. Informal discussions among family members and close friends are not governed by the rules and duties of confidentiality that apply in medical professional relationships, unless secrecy is specifically
required. Individuals may therefore be deterred from making disclosures that they would make in professional settings, such as of contraceptive and other sexual practices and illicit or prescription drug use, for instance for mental health conditions. Similarly, practitioners may not be as guarded as professional practice requires against deliberate or inadvertent disclosures to members of family or close friendship circles whose members share concerns for each other.

6. Gynecologists’ care and/or treatment of family members’ or close friends’ adolescent children can raise issues of particular ethical concern due to adolescents’ sensitivity to revelations they may be asked to make or that may become apparent on examination. Issues of adolescents’ adequately free and informed consent to any such offers of advice and/or intervention can also raise ethical concerns. See FIGO ethical recommendations on Adolescents and Youth Reproductive Health Care and Confidentiality.

7. Greater ethical and legal negligence issues arise if practitioners provide advice and/or treatment while lacking knowledge of recipients’ medical histories, fail to record their interventions including prescriptions with recipients’ primary care physicians, and/or are tempted, by their conscientious interests, to provide advice and/or treatment outside their field of specialization.

8. Professional services are ethically and legally expected to conform to professional standards, for instance of competence, informed and freely-given consent, confidentiality, and follow-up care. Ethical and legal concerns include whether practitioners’ conduct is covered by their professional liability insurance or protection plans, and whether they may charge recipients or recipients’ healthcare insurance providers for their services.

9. Issues of particular complexity, such as propriety and confidentiality, may arise when family members or close friends request advice about a spouse or partner, or an adolescent member of their family.

Recommendations

1. Professional duties should supersede personal relationships, including maintaining confidentiality. Obstetrician/Gynecologists may advise
family members and friends, but undertake to treat them only within ordinary domestic ("band aid") limits, except in cases of emergency or when there is immediate need and no other appropriate healthcare provider is available.

2. Whether advice or care is requested or offered, a professional judgment should be made on examination of potential recipients’ circumstances whether they should be referred to more qualified or specialized practitioners.

3. Practitioners should ensure that potential recipients of their advice and/or care receive accurate and full information, including of sensitive issues, and that they can provide adequately informed consent. They should also ensure that recipients are able to decide free from family, social or other pressure or inducement, such as feeling a need to accept an offer of assistance.

4. When family members or close friends request advice regarding their spouses, partners or, for instance, their adolescent children, practitioners should preferably refrain from offering such advice, but if proceeding should consider whether such third persons should be included in the discussions, or whether to suggest their inclusion.

5. Practitioners should be particularly careful to preserve confidentiality of any advice or care they provide to family members, close friends or others on whose behalf family members or close friends request advice, because disclosures may be requested or pressured, or occur in unguarded discussions.

6. The primary care physicians of recipients of such care should promptly be informed of any treatment or prescription given or refilled, and of any indicated follow-up care that may be required.

7. Any service for which a fee is claimed, and/or for which coverage under a professional insurance or protection plan is claimed, should conform to professional standards, for instance of skill, free and informed consent, confidentiality and provision for follow-up care.

Paris, March 2015
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.

Note 1 See Ethical Guidelines D3 Ethical Guidelines Regarding Interventions for Fetal Well Being.

London, April 1999

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 decisionmaking. 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:
“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.”

3. 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.

4. 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.

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 decisionmaking. 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.

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.

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.

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 recognized 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 recognize 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 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 aware that such confidentiality will be properly protected.

3. 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.

4. 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.

5. 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.
6. Care providers should ensure that access to their facilities, and their facilities’ waiting and counselling areas and treatment rooms, preserve young persons’ confidentiality.

7. 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

HPV VACCINATION AND SCREENING TO ELIMINATE CERVICAL CANCER

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 disproportionally 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 HPV16 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

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 amenorrhoea, 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.

Goa, March 2011

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 HEALTH CARE WORKERS

Background

1. The worldwide shortage of health care workers, coupled with a
disproportionate concentration of health workers in developed nations
and urban areas, and brain drain of health workforce from developing
countries stands in the way of achieving a reduced child and maternal
mortality, increasing vaccine coverage, and battling epidemics such as
HIV/AIDS in the developing countries.

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

3. Shortage and maldistribution of health care workers, aggravated by
brain drain of health workforce from Africa, Asia and pacific countries
to developed countries, contributed to Mothers’ and newborn deaths
and morbidity at vastly different rates in developed and developing
countries.

4. About 35 percent of pregnant women in developing countries have no
access to or contact with health personnel before delivery. Only 57 percent 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. 9.2 million Children die before their fifth birthday-nearly
40% of these in the first month of life. More than 99 percent of all maternal deaths occur in developing countries, with some 84 percent concentrated in sub-Saharan Africa and south Asia where brain drain hits most.

6. Evidence shows that we could save at least seven million of these lives each year with proven, cost-effective interventions that requires the availability, training and retaining of adequate number of health workers. Brain drain creates a bottleneck to improving MNCH and fighting HIV-AIDS, and translates into loss of potential employers, teachers and role models.

7. At least 2.3 trained health care providers are needed per 1000 people to reach 80% of the population with skilled attendance at birth and child immunization. It will take 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 due to largely growing aging population and increasing demand for high-tech care.

8. Developing nations spend $ 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 health workforce from developing to developed countries should be regulated. It deprives source countries from the scarcest human resources, undermines health service and markedly widens the 90/10 Gap between developed and developing countries.
3. Temporary return of qualified health professionals, and their virtual participation through conferences, telecommunication and internets, should be encouraged as it contribute 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 health care technology to developing 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 visa to health professionals from other countries.

6. Developed 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 developing countries.

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

8. In developing countries particularly Sub-Saharan Africa, Southern East Asia and Latin America locally relevant medical training and research should be implemented to address endemic problems with significant mortality like malaria, HIV/STDs, 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 developing countries to increase retention and encourage return to country of origin.

10. Countries which produce excess number of health workforce, 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 (FDI), ensuring that migrants get 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 paying taxation which they were supposed to do had they stayed at home.

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

London, 2009

ETHICAL CONSIDERATIONS ON THE HEALTH CONSEQUENCES OF CHILD OR ADOLESCENT MARRIAGE

Background

1. Early or child marriage is defined as marriage below the age of 18 years. Although this is the age of consent in many jurisdictions, this may be legally lower in others (16 years), or not regulated at all. Despite laws to prevent the practice in many of the countries where it is common, global rates have hardly declined over the past 10 years. Child marriage is considered a violation of human rights whether it happens to a girl or a boy, and it represents one of the prevalent forms of sexual abuse and exploitation [1].

2. The harmful consequences are several, both psychosocial, including separation from family and friends, lack of freedom to interact with peers and participate in community activities, and decreased opportunities for education and medical care, mostly related to the risks of sexual activity and childhood pregnancy (see “Ethical issues in adolescent pregnancies” [2]).

3. Child marriage can also result in the sexual exploitation, and subjection to violence of the female child. It is often a product of gender discrimination that devalues girls.
4. Even where girls are willing to give consent to this life-changing status, consent to underage marriage is not legally valid. This practice may be compatible with the WHO definition of gender-based violence that results in, or is likely to result in, physical, sexual, or mental harm or suffering to women (see “Ethical guidance on healthcare professionals’ responses to violence against women” [3]).

5. In some cases marriage will not be immediately consummated, but in cases where it is, this may fall within the definition of rape.

6. Medically, the risks of teenage pregnancy are well documented (see “Ethical issues in adolescent pregnancies” [2]). Girls’ sexual activity may prejudice their health through sexually transmitted infections, including viruses like HIV and hepatitis, as well as their future sexual and reproductive health.

7. Young brides are also generally more at risk of violence from their domestic or intimate partners, especially if they are geographically or socially marginalized (see “Ethical guidance on healthcare professionals’ responses to violence against women” [3]). Girls may not be immediately forthcoming about violence they have experienced. Gynecologists, midwives, and other healthcare workers may be the first medical persons they encounter in privacy, in the absence of, for instance, husbands or mothers-in-law. Healthcare providers may encounter more girl-bride victims of violence than they realize, and should have a low threshold for enquiring about this possibility.

8. Mandatory reporting of underage marriage varies among jurisdictions. Even where not legally compelled, documenting such an occurrence is often considered useful for awareness and subsequent policy making.

Recommendations

1. Member societies of FIGO should advocate with governments, societies, and families against child marriage, and for the continued education of girls. This includes providing education and helping to create awareness of the complications of early pregnancy.

2. Member societies of FIGO should support the basic and continuing education of all relevant healthcare providers, particularly
gyneologists, obstetricians, midwives, and nurses, in the specific needs and care of girl brides.

3. Member societies of FIGO should promote knowledge about the identification and care of girls who have experienced intimate partner or other violence and sexual assault, which are more common in girl marriage (see “Ethical guidance on healthcare professionals’ responses to violence against women” [3]).

4. Sexual reproductive health services and education should be provided to all children. If girls are married the same rights apply, and they should be counselled on the advantages of postponing pregnancy and be supported in acquiring contraception. Involvement of male partners should similarly be encouraged.

5. Care for married girls should, as far as possible, be integrated into existing services, whilst taking due care of their special need as adolescents. Clinical care should be girl-centered, offering consultation with utmost privacy and maximum confidentiality, in a youth-friendly environment.

6. Healthcare professionals should be trained in diagnosing, documenting, and caring for girls exposed to violence (see “Ethical guidance on healthcare professionals’ responses to violence against women” [3]).

7. When laws forbidding girl marriage are not respected, it is everyone’s duty to highlight this fact without stigmatizing or penalizing the girls.

8. Professional societies should advocate governments to implement the UN Convention on the Rights of the Child [4] where it has not been implemented.

London, March 2014

References

FIGO


ETHICAL ISSUES IN WOMEN’S POST REPRODUCTIVE LIVES

Background

1. The ovary contains a finite number of oocytes that decreases each month or over time. Because of the progressive reduction in oocytes and the associated cells, the endocrine function of the ovaries starts to decline after the age of 40–45 years. When the level of estrogen secreted by the ovaries is too low to stimulate the growth of the endometrium, a woman will stop menstruating.

2. The occurrence of menopause marks the end of the natural reproductive period of women. The reduction in the hormonal secretion from the ovaries may lead to some distressing symptoms such as hot flashes, night sweats, problems with sexual intercourse (because of lack of vaginal secretions). However, the incidence of these symptoms varies among different populations. Many women pass through menopause without significant symptoms. The long-term estrogen deficiency may also lead to osteoporosis with an increased risk of fractures. In addition to the biological changes and physical symptoms, menopause also occurs around the period when changes in life and the family may occur. The children may have grown up and left the family.

3. Some doctors adopt a purely biomedical approach, and consider that the perimenopausal problems are entirely due to estrogen deficiency, to be treated by estrogen therapy. This approach has been criticized by feminist researchers who consider menopause as a normal, life-change
transition with positive aspects and gain for women. Indeed menopausal transition is affected by a combination of biological, psychological, social, and cultural factors. A holistic approach is more appropriate.

4. The management of menopausal transition was complicated by the changes in the scientific evidence in the last decade. Based on early observational studies, it was thought that menopausal hormonal therapy (MHT) with estrogen (with progestogen in women who still have a uterus) could relieve climacteric symptoms, prevent the occurrence of osteoporosis, fractures, and heart disease. Therefore, it was advocated that all women except those with contraindications should take estrogen after menopause. The publication of two randomized studies [1,2] showed that the risks of MHT outweighed the benefits, and the risk of development of cardiovascular diseases was increased in women more than 10 years from menopause. The risk of development of breast cancer in the combination arm was also increased. These led to the marked drop in the use of hormone replacement therapy (HRT).

5. However, subsequent reanalysis of the data showed that in women younger than 60 years and within 10 years of menopause, estrogen alone may lead to a reduction in coronary heart disease and mortality from all causes, while estrogen plus progestogen does not cause a significant decrease or increase in coronary heart disease. Such rapid changes in opinion have caused confusion among women as well as healthcare providers. This was made worse by some differences in the MHT guidelines from different professional bodies and the perception that some doctors were promoting MHT on behalf of drug companies. In 2012, many menopause societies got together and issued a Global Consensus Statement on Menopausal Hormonal Treatment [3]. It is hoped that this will reduce the confusion among healthcare providers and women.

6. About 50% of postmenopausal women experience symptoms such as dyspareunia and postcoital bleeding as a result of vulvovaginal atrophy. However, women are often uncomfortable in discussing these symptoms because of embarrassment; some women may not know that MHT is effective and safe treatment. Healthcare providers are usually not proactive in initiating discussion in this area because of inadequate
or omitted training, inadequate time at busy clinics, and a personal attitude that sexual activity is not important for older women.

7. Menopausal transition provides an opportunity for introduction of effective health promotional programs. Lack of resources and gender inequality in many low-resource countries make it difficult for women with low income to access appropriate healthcare programs.

**Recommendations**

1. Healthcare authorities should ensure that adequate resources be provided for menopausal clinics and other health promotion programs for postmenopausal women.

2. Women should be educated about the normal physiological changes during the menopausal transition and the problems that may arise and how they can be managed.

3. Member societies should act as advocates for women and lobby the appropriate authorities to ensure proper provision of health care for postmenopausal women. Based on the global consensus statement on MHT, member societies should issue appropriate guidelines to their members on the management of perimenopausal and postmenopausal women.

4. Healthcare providers should undergo training to ensure that they can provide proper care for the climacteric problems of postmenopausal women. As the menopausal transition may be affected by biological, psychological, social, and cultural factors, it is important to adopt a holistic approach in the management of climacteric problems of postmenopausal women.

5. Healthcare providers should be proactive in initiating discussion of menopausal symptoms especially in the area of sexual problems irrespective of their personal beliefs, as women often feel embarrassed to initiate discussion on intimate topics.

6. Healthcare providers should ensure that they are familiar with the most updated information including the local guidelines on menopausal problems and their management.
7. In scientific discourse and public health education, healthcare providers should provide accurate and objective information. If there is any potential for conflict of interest, it should be declared (see FIGO recommendations on “Conflict of interest”).

London, March 2014

References


PATIENTS’ REFUSAL OF RECOMMENDED TREATMENT

Background

1. Treatment may ethically be provided to patients only with their informed consent. It follows that, if they refuse consent to recommended treatments, such treatments usually cannot ethically be imposed upon them. The clinical management of patients’ refusals of recommended treatment raises ethical concerns regarding informed refusal, patients’ mental and legal capacity to make their decisions, and whether refusals may be overridden by, for instance, parental or other authority, or courts of law.

2. No third party can forbid recommended treatment on behalf of a competent adult or adolescent patient who gives consent to it, and anyone legally required to meet the costs of the patient’s necessary care who has the means to pay but refuses may face legal liability for failure to provide care necessary to life.
3. Refusals may be, for instance, of blood transfusion or the use of blood products such as albumin, and be based on religious, cultural, philosophical, or other convictions. Even when based on apparently irrational, mistaken, or confused grounds, however, refusals warrant respect, and in law, imposing treatment contrary to patients’ refusals, whatever their basis, is likely to constitute a civil (non-criminal) wrong such as assault, and even a crime.

4. Patients may refuse recommended treatment at the time when it is offered, and may also prepare advance directives that show what medical treatments they intend in the future to accept or refuse, and/or who is to make and/or express choices on their behalf when they are incapable of forming and/or expressing their wishes. Such advance directives may be general refusals for instance of blood transfusion and blood-derived products, but advance directives based on legislation often focus on end-of-life care. Advance directives may similarly apply, however, in gynecology and obstetrics when patients face, for instance, childbirth involving episiotomy or heavy blood loss, or gynecologic surgery under anesthetic.

5. Patients must ethically be offered appropriate information to make their medical decisions. The ethical purpose of informing patients is not to induce their consent, but to aid informed decisions. Patients may freely decline this offer, and consent to recommended treatments by trusting their physicians without further explanation. If they refuse indicated treatment recommended to them in their best interests, however, providers must ensure that they understand why it is recommended, and the implications for their health of forgoing treatment or having alternative treatment. Providers must also ensure that patients understand the implications of their decisions for others for whom they care, such as their dependent and/or future children.

6. Patients who refuse recommended treatments but voluntarily maintain their doctor–patient relationships cannot be abandoned. Every effort must be made to provide alternative care acceptable to the individual patient that meets professional standards. This may include, for instance, surgery without blood transfusion, use of synthetic blood substitutes, or when feasible and acceptable to patients, recovery and reinfusion of their own blood. Patients who refuse cesarean deliveries must be assisted in natural delivery. Providers commit no ethical or
legal breach in complying with informed patients’ freely chosen refusals of recommended care, even when the patients’ lives are in peril.

7. Patients’ refusals of recommended treatments may raise issues of patients’ decision-making capacity. Mental incapacity is often stigmatizing, and should not be presumed from refusals. Patients may be asked their reasons for refusing recommended treatments, to determine whether their refusals are based on misunderstandings that may be corrected. However, patients cannot be compelled to give reasons for their refusals, and even those that appear emotional and irrational or neurotic are ethically and legally binding. Mature adolescents’ refusals cannot ethically be overridden by parental authority (See FIGO recommendations on “Adolescent and youth reproductive health care and confidentiality”). Treatment cannot usually be imposed even when patients’ reasons for refusal disclose more serious mental disorders, bordering on psychosis, but any legally empowered substitute decision-makers should then be sought in preference to requesting judicial decisions on patients’ mental competency.

8. As an exception to the informed consent requirements above, in emergency situations where consent cannot be obtained from or on behalf of the patient or by court authorization and there is no knowledge of the patient’s preferences, emergency treatment should proceed based on reasonably implied consent. Further, in emergencies when patients’ lives or continuing health are in immediate danger, such as during childbirth, treatment may be given even contrary to previous agreements, but this is not ethically obligatory. Any proposed exceptional treatment without court approval, on the presumption of patients’ reasonably implied consent, or that overrides a refusal of treatment, should be subject to prior independent review of its medical necessity or, when prior review is not possible, prompt independent subsequent review.

9. It is permissible to request patients in advance to absolve providers from legal liability for compliance with their informed refusals of recommended treatments. However, care appropriate in the circumstances cannot ethically be denied simply because patients decline requests for providers’ release from legal liability for compliance with patients’ refusals. Patients’ informed acceptance of
the risks of forgoing indicated care precludes providers’ legal liability for reasonably foreseeable consequences (see 6 above).

10. The discussion of ethical approaches above is applicable in principle to patients’ refusals of elective diagnostic tests, for instance conducted on their tissue or other samples.

11. Providers whose patients refuse their recommendations for care may refer them for additional opinion if desired by the patients or, preferably with the patients’ consent, refer them to other accessible providers in their own departments or facilities, or in other facilities, provided that they ensure continuity of patients’ care.

Recommendations

1. Practitioners should explain to their patients why they recommend particular treatments in terms their patients can understand, but accept their patients’ rights to informed refusal.

2. Practitioners should offer to inform refusing patients about the implications for their health of failure to undergo recommended treatments, about available alternative treatments, and their prognoses if they withdraw from undertaking any treatment.

3. Practitioners should not presume that a patient’s refusal of recommended treatment is due to the patient’s intellectual failure to understand why it is recommended.

4. Intellectually mature minors’ decisions to refuse or consent to recommended treatments should not be allowed to be overridden by parents’ or guardians’ preferences.

5. If, after appropriate testing, patients seem to lack intellectual capacity to make treatment decisions for themselves, practitioners should enquire whether patients have designated other persons, such as family members, to express or make medical treatment decisions for them.

6. If there continues to be concern over the patient’s capacity to make treatment decisions, and no substitute decision-maker is identified or gives consent, the discretion to seek judicial approval to override a
refusal of recommended treatment by, or on behalf of, a patient should be exercised only if consultation shows the patient’s life or continuing health to be at serious risk.

7. If a patient lacks capacity and a substitute decision-maker is unavailable or a judicial application is not feasible, any treatment overriding the patient’s refusal should be considered only in an emergency endangering the patient’s life or continuing health, and preceded, or if this is not possible then followed, by an independent review.

8. No third party should be allowed to refuse administration of necessary treatment to which a mentally competent patient consents.

9. A provider whose patient refuses recommended treatment may transfer responsibility for the patient’s further care to another suitable provider, on the condition that continuity of patient care is maintained.

London, March 2014

ETHICAL HEALTH CARE OF SEX WORKERS

Sex workers should receive appropriate care without discrimination

Background

1. Human rights to non-discrimination and equality underpin the entitlement of all women, regardless of health, social or economic status, to medically-indicated care and to receive treatment non-judgmentally and with dignity.

2. The FIGO Ethical Framework for Gynecologic and Obstetric Care reinforces this entitlement by providing (para. 6) that “In the delivery of health care to women, justice requires that all be treated with equal consideration, irrespective of their socioeconomic status.”

3. The FIGO recommendations on Harmful Stereotyping of Women in Health Care provide (rec. 5) that “Healthcare providers must be vigilant to recognize and redress their own tendencies to approach women patients...through restrictive or negative stereotypes. They should promote women’s dignity and rights to pursue self-fulfillment.”
4. Women sex workers, including those who provide lawful and/or unlawful sexual services or entertainment, are entitled to medically-indicated preventive and therapeutic care in non-judgmental, professional settings, without prejudicial stereotyping or stigma.

5. Sex workers may be victims of sexual and other exploitation, trafficking and/or violence, legally more offended against than offending, warranting compassion and such protection as healthcare professionals can reasonably provide.

6. Where patients indicate that they are not in sex work voluntarily, they should first be provided with indicated care, and then be advised on sources of relief. Whether they act voluntarily or not, they need to be made aware of the hazards of high risk behavior related to their occupation, and of protective means. As commercial sex-workers, women need to understand that they are at high risk of contracting disabling sexually transmitted infections, unwanted pregnancies leading to unsafe abortions, having no rights or powers to insist that their clients use condoms, a debased social status, and other risks to their health.

7. Providers and medical associations have responsibilities to support their governments and societies to identify and relieve abuse of sex workers, and to engage in providing options for women to earn their livelihood by other means.

**Recommendations**

1. Practitioners should respond to requests for care by women disclosing sex work occupations non-judgmentally and without discrimination, for instance by not separating them from other patients. Any extra risk of them contracting, and spreading, infections such as HIV and hepatitis should be appropriately contained.

2. Where such patients disclose subjection to sexual or other violence, practitioners should observe the FIGO Ethical Guidance on Healthcare Professionals’ Responses to Violence Against Women. Health care workers should be vigilant in detection of signs of violence in such patients.
3. Practitioners should be proactive in offering advice on prevention and screening of sexually transmitted infections.

4. If patients are or appear to be children as defined by prevailing law, practitioners should observe any governmental reporting obligations under child protection laws, for instance concerning child abuse or neglect, and children in need of protection.

5. If those accompanying such patients are covering expenses of their care, patients should be separated from them and then asked whether their companions exercise unwanted control or influence over them. If patients reply positively, they should be asked whether law-enforcement or other authorities should be informed.

6. Practitioners may be the first to whom women disclose that they are not in sex work voluntarily, and should consider how such women’s circumstances may be mitigated, and offer them assistance to pursue alternatives.

7. FIGO member societies have responsibilities to educate their members about the rights of sex workers to non-discrimination, and the medical risks they face. They should advocate that no coercion, trafficking or other exploitation of sex workers is condoned in their societies, and for options that allow sex workers alternative viable means of earning a livelihood if they want them.

Paris, 2015

B. ISSUES 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.

7. 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 resources 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.

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 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 genetic 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 genetic alteration of somatic cells to treat disease (gene therapy), germ line genetic alteration, and non therapeutic genetic alteration (genetic enhancement).
4. Genetic alteration of somatic cells to treat disease
   (i) Since the altered genetic material is not inserted into the germ cells, the alteration is not passed on to future generations. Somatic genetic 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 gene 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.

Lyons, 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 cybrid 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
C. ISSUES IN CONCEPTION AND REPRODUCTION

ETHICAL GUIDELINES ON MULTIPLE PREGNANCY

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.
9. 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.

1Note: Donation of Genetic Material for Human Reproduction 1993. Published Int 

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 contra-indication 
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 at the heart of 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, 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 breastmilk 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.

London, 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, 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

D. ISSUES IN 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

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\(^3\).
Note 1. Verification of this is usually only possible at the present time at 3 weeks or more after implantation.
Note 2. WHO definition of a birth: 22 weeks’ menstrual age or more
Note 3. In some cases the dead products of conception may be reabsorbed or retained.

_Cairo, March 1998_

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 counseling, 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 may be 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, over 273,400 women die – about 750 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 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 4% of all maternal deaths overall, but up to 20% or 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.

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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 D.12 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, 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 post-partum 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.

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.

London, 2012
ETHICAL ISSUES IN ADOLESCENT PREGNANCIES

Background

1. Adolescence is the timeframe during which a combination of physical, psychological, and social changes occurs. According to the United Nations, each year 16 million girls under the age of 18 years give birth, accounting for more than 10% of births worldwide.

2. Adolescent pregnancies occur because of early exposure to sexual activity, especially in high-income regions or within early marriages in certain cultures and ethnic groups. Lack of knowledge of contraception and of access to quality reproductive and sexual health information, and lack of access to reproductive health services that respond to needs of adolescents, both female and male, add to the risk of unwanted pregnancies.

3. Adolescent pregnancies accounted for approximately over 70 000 maternal deaths (i.e. 25% of total maternal deaths) in 2013.

4. The vulnerable groups belong to the low socioeconomic strata of societies, and include adolescents who do not complete their education or have low levels of education, victims of domestic violence, the mentally challenged, those with easy access to substances they abuse, and quite often those whose parents have themselves married during their teenage years.

5. Adolescent pregnancies may be unplanned or within early marriage, as seen by the 2.2 to 4 million (10%) teenage girls every year who obtain abortion services. Unplanned adolescent pregnancies in single mothers contribute greatly to unsafe abortions, maternal mortality, and maternal morbidity. Pregnancies that are continued to birth are usually those that occur within marriage or that are detected late in pregnancy by uninformed single adolescents.

6. Evidence suggests that pregnancies, particularly in the very young, have a negative impact and contribute to higher dropout rates from school, affecting girls’ education. This limits their job opportunities and financial self-sufficiency, leading to poverty and an increased risk of repetitive pregnancies.
7. Adolescent pregnancies cause adverse outcomes, especially in the 13–16-years age group, with the risks being higher in younger adolescents with poor nutrition and immature physical development.

8. Pregnancies during the adolescent period have adverse effects on both the mothers and the children. Besides anemia and a low nutrition status, there are added complications such as pregnancy-induced hypertension, obstructed labor, obstetric fistula, postnatal depression, and other morbidities that are mainly due to the biological and gynecological immaturity of this age group. Continuation of pregnancies often leads to premature deliveries, low birth-weight babies, and increased neonatal morbidity and mortality.

9. There is evidence that teenage mothers often have mothers who themselves had adolescent pregnancies. There is a risk of this cycle repeating itself. The offspring of adolescents are known to have poorer cognitive development, lower educational achievement, and a higher rate of criminal activity. As children, they are also at a higher risk of suffering abuse, neglect, and behavioral problems.

10. In certain cultures, unmarried adolescents fear harsh consequences of disclosing their pregnancies to their parents, such as social ostracism. They therefore seek abortion, or may develop suicidal tendencies. Abortions in adolescents can be legal or illegal, with varying morbidity and mortality depending on the laws in the countries in which they reside.

11. Their unawareness of contraceptive options and lack of access to legal and safe abortions may expose pregnant adolescents to the risks of unsafe abortions.

Recommendations

1. Healthcare professionals, along with governmental and nongovernmental organizations, should ethically ensure reproductive and sexual health education, and advocate such education both inside and outside schools. This education should be comprehensive and easily accessible by adolescents and their parents to increase their awareness about the risks of unprotected sex and unwanted pregnancies, the complications associated with pregnancies at such an early age, and availability of early and safe abortion where legal.
2. Health professionals should advocate for pregnant adolescents’ opportunities to complete their schooling to maximize their chances of achieving self-sufficiency in the future.

3. Adolescents’ access to reproductive and sexual health information and services should be made available, and outreach programs should be developed in rural areas, supporting adolescents to make decisions over their own bodies.

4. According to the UN Convention on the Rights of the Child, parental consent should not be necessary for termination of pregnancy of young girls intellectually capable of giving informed consent themselves, though it would be advisable with their agreement to involve their parents in their decision-making. Healthcare workers should attempt discussions with pregnant teenagers regarding their future, including their needs for completion of education, financial stability, and good health.

5. Adolescents should be provided with access to quality reproductive and sexual health services, along with postabortion and postpartum care.

6. Adolescents should be assured that their needs for appropriate care will be met and that their rights to confidentiality will be respected.

7. Professional societies should work with governmental health departments to encourage inclusion of adolescent-friendly health service protocols in the pre- and in-service training curricula of all levels of health service providers.

*London, March 2014*

**References**


E. ISSUES REGARDING NEONATES

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 vs 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
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 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

ETHICAL ASPECTS OF THE INTRODUCTION OF CONTRACEPTIVE METHODS FOR WOMEN

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 intra-uterine 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).¹

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

153
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.²

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.

Note 1: This is not relevant to the lethally malformed fetus, cf Ethical Aspects of the Management of the Severely Malformed Fetus, Int.J. Gynecol. Obstet,


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”.

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
G. ISSUES IN ADVERTISING & 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

RECOMMENDATIONS ON CONFLICT OF INTEREST, INCLUDING RELATIONSHIPS WITH INDUSTRY

Background

1. Medical professionals have distinctive ethical responsibilities directly to their individual patients, and to the wider population of indirect consumers of their services that has confidence in their impartial judgment, to avoid or resolve conflicts of interest. Furthermore, they often have specific responsibilities as members of professional societies and/or universities, and as participants in educational activities, whether local, national, or international.

2. Conflicts of interest arise when medical professionals give priority to their own professional or personal interests over the interests of their patients and others who rely upon their integrity, whether their interests are financial or otherwise. In nonprofessional, commercial relationships, parties each legitimately pursue and protect only their own interests, under a “let the buyer beware” (caveat emptor) rule. In their professional relationships, however, medical professionals are expected to give priority to their patients’ interests over their own, and not to exploit the power they derive from their superior knowledge and influence for their own advantage.
3. Ethically questionable conflict does not require evidence of medical professionals’ actual corrupt promotion of their self-interest, but only a reasonable concern that biased judgment could occur. An appearance of conflict of interest, such as receipt of gifts, meals, or travel opportunities from commercial manufacturers, jeopardizes public trust not only in particular medical professionals, but also in the medical profession collectively.

4. Conflict is identified by asking whether reasonable observers of medical professionals’ relationships, for example when physicians hold shares in drug companies or receive fees as consultants to industry, would consider that the relationships might bias the physicians to serve their self-interest over the interests of their patients or of the wider community. Risk of medical professionals favoring their self-interest raises obvious ethical concerns, but conflict can appear through other motivations, such as promotion of personal beliefs.

5. Examples of physicians appearing able to favor their own interests over patients’ interests may be drawn from the breadth of professional activities. They include physicians having financial investments in manufacturers of products they may prescribe, serving as consultants to drug or medical device companies, commercially promoting nontherapeutic services (see FIGO’s “Ethical considerations regarding requests and offering of cosmetic genital surgery”), forming romantic or sexual relationships with patients (see FIGO’s “Some ethical issues in the doctor–patient relationship”), and advising one’s patient from a public health facility to attend one’s private fee-paying clinic (self-referral). Fee-splitting with colleagues to whom physicians refer their patients is ethically prohibited because it presents bias of referral to colleagues who provide greater shares of fees than to others whose skills would better serve the interests of referred patients.

6. In undertaking or assessing scientific research, making professional conference presentations, serving as members of professional societies, writing, editing or reviewing professional literature, and, for instance, teaching or student supervision, there are also potential conflicts of interest, such as presenting only positive study results. Nondisclosure of financial or other interests may mask goals of self-interest and falsely imply disinterest and objectivity, inducing the unjustified confidence of others such as professional colleagues, governmental regulators, students, and readers.
7. Nonfinancial conflict of interest arises, for instance, when physicians exclude from disclosure of patients’ choices of treatment any medical procedures to which the physicians are conscientiously opposed, such as abortion, or when they object to participation in such procedures without referring patients to nonobjecting providers (see FIGO’s “Ethical guidelines on conscientious objection”). Nondisclosure of medical errors may violate duties of truth-telling to patients to serve self-interests in avoiding embarrassment or litigation (see FIGO’s recommendations on “Disclosing adverse outcomes in medical care”).

8. An appearance of potential conflict of interest is often unavoidable. In fee-for-service delivery of care, for instance, fees may be based on what individual patients are able to pay, such as through their health insurance schemes, rather than on scheduled rates. Fee income can be increased by recommending unnecessarily frequent follow-up appointments. Similarly, busy salaried providers may reduce the burden of services they are responsible to deliver by scheduling follow-up visits at too prolonged intervals. In either case, providers may appear to exploit patients’ dependency and disadvantage to serve their own interests. Medical licensing authorities and/or professional associations with disciplinary powers may review whether providers are setting exorbitant fees or departing from medically indicated frequency of follow-up care.

9. Relationships with professional colleagues may create conflicts of interest. Collegiality among physicians is frequently in patients’ interests, for instance in hospital and clinic settings where providers treat patients in teams. This may present conflicts of interest, however, when physicians give primary allegiance to colleagues rather than to patients. Providers may remedy or relieve errors made by their colleagues, to patients’ advantage, but may also gain self-serving interests in comfortable relationships with colleagues to conceal or deny such errors, and to tolerate colleagues’ substandard performance of their responsibilities. They may similarly be motivated to protect their departments’, hospitals’, or clinics’ reputations rather than expose deficiencies that place patients’ interests at risk.

10. Conflicts of commitment differ from conflicts of interest. When physicians receive no personal benefit for instance from giving priority to some patients over others, or from giving time to instructing
students over attending committees on which they have responsibilities, or vice versa, that is, when they are disinterested in which interest they prioritize, their conflicts are in choice among alternative commitments. How they resolve these conflicts also raise ethical concerns, but not physicians’ ethical condemnation for succumbing to self-interest.

11. Conflicts of interest may be avoided, such as by divestment of suspect relationships, but conflicts that cannot be avoided may be resolved or reduced by appropriate disclosure and transparency. Disclosure to patients of their physicians’ investments in or consultancies to drug companies may not protect patients’ interests when company products may be prescribed, since patients usually lack means of independent judgment. Physicians may have to disclose their conflicts for instance to institutional superiors, professional associations, and licensing authorities, or at least to their colleagues. Disclosure of relationships with industrial and other manufacturers is ethically required in any professional evaluation of their products in publications and/or other communications, including professional presentations at conferences.

Recommendations

1. Physicians should be alert to financial and other conflicts of interest in their professional practice and relationships, avoid such conflicts when they can, and make appropriate disclosures of conflicts that they cannot avoid, for instance to institutional superiors or professional oversight authorities or associations, and in professional conference presentations. Any proposed referral of one’s patient from a public health facility to one’s private clinic should be disclosed and justified to the administration of the public facility, and/or to one’s appropriate professional oversight authority.

2. Physicians should continually review their own direct and indirect financial and/or other conflicts of interest to ensure that they are not improperly influenced in the prescribing or promotion of drugs, devices, or other appliances. They should be associated only with treatments that have been peer reviewed or that have been investigated under careful appropriate methodology.

3. Physicians should charge fees for their services only that are reasonable according to professional standards, such as by reference to publicized
fee schedules, and conform to professional standards in scheduling frequency of post-treatment care, in order not to appear to exploit patients for self-interest.

4. Physicians’ status as consultants, investigators, or holders of proprietary interests in development or use of drugs, medical devices, or other medical products or procedures should be disclosed as a financial or other interest in any professional evaluation and/or use they make of such drugs, devices, products, or procedures, for instance in publications and conference presentations.

5. Publishers of professional evaluations of drugs, medical devices, or other medical products or procedures should ask authors to disclose any conflicts of interest. Sponsors of medical conferences, meetings, workshops, and the like should publicly disclose any conflicts of interest they have, and ask presenters to disclose any conflicts of interest they have.

London, March 2014

ETHICAL CONSIDERATIONS REGARDING REQUESTS AND OFFERING OF COSMETIC GENITAL SURGERY

Background
1. Female genital cosmetic surgery is surgery performed on women who are physically healthy and whose genitalia are within the normal range of variation of human anatomy. Female genital cosmetic surgery does not have a medical indication, but rather is sought out to meet an individual cosmetic goal. By contrast, surgery for known medical indications, such as to address physical dysfunction and discomfort that limits normal function, is therapeutic (such as repair of fistula, surgical scarring, infections from scarring).

2. Surgery that intervenes to change appearance or to impact function on physically healthy women is considered nontherapeutic and is the focus of cosmetic genital surgery. This is generally differentiated from female genital cutting, circumcision, or mutilation, which also alters normative anatomy, by the active and voluntary surgical consent of women undergoing cosmetic procedures.

3. There is a wide variation of normal vulvar and vaginal anatomy. Education about normative anatomy particularly for sexual and
reproductive functions is lacking worldwide. Women, their partners, and health professionals may be influenced by an increasing media focus on only small areas of the normal range, particularly adolescent or prepubertal genital appearance, into thinking this narrow range is ideal anatomy.

4. Ethical concerns have been raised regarding the performance of medically unnecessary surgery (elective surgery) on healthy women, particularly when women falsely believe that their genitalia are abnormal, that only a small range of anatomy is normal, and that “normality” or “normal function” can be achieved by surgical means.

5. Ethical concerns further arise if promotional advertising by members of the profession induces an unjustified belief that normal women’s genital appearance or function is abnormal. There is a direct conflict of interest if the promotional materials induce a belief that there is an abnormality that would then be addressed by the gynecologist advertising the procedures.

6. Cosmetic surgery in general and cosmetic genital surgery have the inherent risk of attracting patients who have body dysmorphic disorders and other psychological disorders and so perceive their anatomy as abnormal even if normal. Failure to recognize this underlying psychological disorder creates long term harm to patients, both by exposing them to risks of surgery and by failing to recognize and treat an underlying psychological medical condition.

7. Beyond the standard surgical risks of infection, bleeding, and scarring that disrupt normal function, the unique risks of these surgeries are yet to be well described with long-term and robust studies discovering, describing, and validating short-term and long-term benefits and harms. Additionally, the expectations of patients for cosmetic, sexual, social, and/or other advantages may not be achieved. All of these are important disclosures for women to consider in making such decisions.

8. Failure to share knowledge regarding distinctive techniques openly with professional colleagues, and to thereby allow independent repetition of techniques to validate outcomes, adds to the lack of effectiveness data. This violates medical professional duties of transparency, of allowing independent peer review, and of inclusive teaching.

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9. A wider ethical concern, at a national and international level, is the impact of diversion of skilled gynecologic talent toward cosmetic surgery when the needs of women for necessary gynecologic services remain unmet. This inequity raises local and global health ethics questions concerning equity of access to essential services that require all levels of service providers to justify this practice.

10. There is an additional human rights concern that the right to self-choice and autonomous decision-making may be interfered with by inadequate education, personal or cultural coercion from partners with limited knowledge of genital normative anatomy, or inability of women to make their healthcare choices. Lack of economic independence may further inhibit autonomous decision-making, particularly when the nontherapeutic change in appearance or supposed change in sexual function is linked to the woman’s personal and economic well-being.

Recommendations

1. Gynecologists must differentiate between therapeutic and medically nonindicated or cosmetic genital surgery, and assure that women seeking such surgeries are able to distinguish the difference. As part of informed consent and respect for autonomous decision-making, they must seek to dissuade patients from unjustified beliefs regarding unsupported sexual, social, or functional outcomes of cosmetic genital surgery.

2. Professional societies, standard-setting organizations, and credentialing bodies have a responsibility to monitor and issue standards for cosmetic gynecologic surgery, indicating whether it may ethically be recommended, and create guidelines for members regarding media portrayal or advertising for female genital cosmetic surgery that reflects the evidence base and normative anatomy. They additionally have a responsibility to promote education in basic normative genital anatomy and function.

3. All gynecologists, having acquired the skills for surgery through the gift of having women consent to inclusion in procedures in order to advance their skills, have an obligation to assure that women continue to have access to medically indicated procedures. The availability of and women’s access to needed gynecologic procedures ethically takes precedence over access to cosmetic procedures.
4. Advertising and enticements for cosmetic surgery can easily cross the line into unprofessional conflict of interest, and should be avoided. Ethically, the goal must remain a medical professional model of practice for the benefit and protection of patients, rather than a competitive business or commercial model designed to maximize investor income.

5. Gynecologists must ensure that a woman’s decision for surgery is informed by adequate knowledge of normative anatomy and function. A gynecologist must disclose the potential for dysfunction from surgery itself, the related risks, and the state of evidence of risks and benefits of the surgery proposed.

6. Physicians practicing in an area where evidence of efficacy and complications is limited have a heightened obligation for patient safety to be transparent regarding the procedures they provide, as well as to contribute to research and systematic outcome monitoring for these procedures. These data need to be peer reviewed and published to establish the evidence for safe practices.

7. If offering cosmetic genital surgery, the gynecologist must have knowledge of body dysmorphic and other disorders that may influence desires for surgery, and appropriately refer women with these disorders for appropriate support and treatment, as part of their ethical responsibility for adequately informed consent.

8. Gynecologists who intend to offer cosmetic surgical procedures must also meet the standard training required not only for cosmetic and/or plastic surgery in this area but also for the exploration of underlying disorders such as body dysmorphic disorders before offering such procedures.

London, March 2014

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 in 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 purview 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.

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H. 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

CONSCIENTIOUS OBJECTION IN TRAINING

Background

1. The primary commitment of obstetrician/gynecologists and those in training is to serve women’s reproductive health and well-being and foster a depth of knowledge that will allow them to offer the highest quality and safety of care possible both during training and when they are certified, whether in obstetrics/gynecology or in another specialty.

2. Medical students and postgraduate trainees may find themselves unable to train to deliver certain medically indicated care for reasons of their personal conscience.

3. Students and postgraduate trainees bear ethical responsibilities to women in whose care they are involved during training, and to the women who will expect a level of knowledge and training when they are qualified to practice.

4. Students and postgraduate trainees have duties to inform their teachers and/or supervisors of their conscientious objections in a timely fashion, to assure that alternate arrangements can be made to insure appropriate care of patients.
5. Students and postgraduate trainees have duties to inform their patients of all medically indicated options for their care, including options in which they decline to participate.

6. Students and postgraduate trainees are ethically bound to develop broad knowledge of medicine and reproductive science in order to apply this understanding to present and future patient care, and to not superimpose characterizations of procedures based on their personal beliefs that differ from professionally accepted medical evidence and/or guidelines.

7. When in an emergency, a patient’s life, or physical or mental health, can be preserved only by a procedure in which the student or postgraduate trainee usually objects to participate, and they cannot find a non-objecting trainee to render critical assistance in a timely way, the trainee, like a practitioner, must give priority to the patient’s life, health, and well-being by performing or participating in the indicated procedure.

Guidelines

1. The primary conscientious duty of trainees in obstetrics and gynecology is at all times to treat, or provide benefit and prevent harm to, the patients in whose care they are involved. Any conscientious objection to treating a patient is secondary to this primary duty.

2. Provision of benefit and prevention of harm require that trainees assist in providing such patients with timely access to medical services, giving accurate information about the medically indicated options for their care, including any such procedures or care in which the trainee objects to participate on grounds of conscience.

3. Trainees have a professional duty to develop knowledge in and 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 their personal beliefs.

4. Trainees 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. Trainees’ right to respect for their choices in the medical procedures and care in which they participate requires that they respect patient choices within the medically indicated options for their care.

6. Trainees cannot decline training in procedures being performed for medically indicated purposes to which they cannot or do not object even though the same procedures can be used for medical indications to which they object. They should be trained, for instance, in management of abortion complications.

7. When in an emergency, a patient’s life, or physical or mental health, can be preserved only by a procedure in which the student or postgraduate trainee usually objects to participate, and they cannot find a non-objecting trainee to render critical assistance in a timely way, the trainee, like a practitioner, must give priority to the patient’s life, health, and well-being by performing or participating in the indicated procedure.

London, March 2014

ASSESSING ETHICAL AND PEER REVIEW STANDARDS OF MEDICAL JOURNALS

Care must be taken to distinguish between reputable and unethically exploitative medical journals to assure use of the highest level of evidence and avoid harm from unreliable information.

Background

1. Learning and teaching are obligations of conscientious medical practice, the title “doctor” being a Latin word for “teacher”. Medical publication ethically contributes to the spread of and access to knowledge. Journals published by leading medical associations and publishers provide reliable, contemporary information of research findings and opinion to practitioners, in general and specialized medical care, to medical students and to the general public. Contributions to such journals may add prestige to their authors, and authors’ research, academic and service delivery institutions.
2. A barrier to medical libraries’, practitioners’ and students’ access to journals may be costs of subscription related to production, printing and mailing expenses.

3. One response to the costs of production has been development of open-access electronic publications, which are free to consumers since production costs are borne by others.

4. Reputable journals may provide for readers’ unpaid access through the journals’ own funding sources, regular subscriptions and/or purchase of individual editions or articles, or for readers’ free access through contributors’ payments as individuals or through their institutional or research funding. The journals review submissions without knowing whether readers’ access would be by one or other of such means, so that acceptance for publication is decided on scientific or academic merit alone, uninfluenced by commercial considerations.

5. In contrast to reputable print and/or electronic medical journals is the emerging growth of unethical, predatory journals whose primary if not exclusive goal is not the spread of medical or other information, but profits from contributors’ payments of “processing fees.” They exploit potential contributors’ personal, institutional or research funds, and are becoming increasingly sophisticated in simulating bona fide journals. Many can be traced through the work of Professor Jeffrey Beall, at the University of Colorado, in Beall’s List (http://scholarlyoa.com/).

6. Such journals may lure conscientious and naïve contributors into submission of research or other texts. Lacking credible peer-review, they are liable to publish “junk science,” irresponsible, worthless opinion pieces, and plagiarised material. They may similarly lure conscientious scientists and practitioners into joining their editorial boards and recruiting submissions. They are not necessarily operated from the editorial addresses they provide.

7. Characteristics of such journals are becoming more clear. Methods to attract submissions include approaching authors published in reputable journals, inviting submissions targeted to their area of research. They promise competent peer-review, which is frequently minimal or non-existent, a short turnaround time to publication, and widespread dissemination, including citation in credible indexes. Acceptance is
conditional on satisfaction of payment requirements, although invoices may be sent after electronic publication, for substantial amounts.

8. Many open-access journals operate in good faith, and legitimately contribute to scientific knowledge. However, there are also unscrupulous, unethical publishers that abuse open-access publishing by exploiting contributors and their funding sources, and corrupt the peer-review process. Some are obvious to informed authors and readers, but others skilfully mirror websites of prominent mainstream journals.

9. Fraudulent journals, which now number in their hundreds, allow researchers and practitioners, many acting in good faith, to grow their curricula vitae, but cause harm to both the authors, by denying them competent peer review, and to the goal of advancing reliable knowledge in women’s health care. Non-experts conducting online research cannot distinguish credible research or opinions from junk science and irresponsible views. They become victims of deception and errors through which, by incorporating this material into their own publications, they may inadvertently deceive others. In healthcare, they may cause harm to patients by treatment based on scientifically flawed or unscientific data.

Recommendations

1. Those considering submissions to journals with which they are unfamiliar, and/or accepting invitations to join their editorial boards, have a responsibility to research the journals’ origins and credibility, and check them for instance through Beall’s List (http://scholarlyoa.com/).

2. Researchers and practitioners, their institutions and funding agencies should not risk the expenditure of effort and resources in submissions to questionable journals, and ensure that any requirements to pay processing fees are determined before proceeding.

3. Researchers and practitioners should guard themselves against journals that promise rapid publication, since in many cases this is achievable only through an absence of proper, or any, peer-review.
4. Researchers, practitioners and students should beware of accessing and relying on publications in journals that are likely to contain unreviewed (“junk”) science and/or irresponsible opinions. Unfamiliar sources of information, however plausible they may appear, should always be critically reviewed for reliability and corroboration from literature in main journals.

5. Authors should be cautious in citing others’ publications in their references, confining themselves to researching in journals published by medical and related associations or reputable medical or wider health institutions and publishing houses.

6. FIGO member associations should undertake a responsibility to ensure that clinicians, researchers and patient advocates receive access to and contribute to high quality professional literature that promotes women’s health care. They should also generate and disseminate knowledge of the types of open access and other publications that fail to satisfy professional standards of reliable information for patient care.