

# Ethics and Professionalism Guidelines for Obstetrics and Gynecology

Edited by Frank A. Chervenak and Laurence B. McCullough

Second edition

# FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology

Edited by Frank A. Chervenak, M.D., M.M.M., and Laurence B. McCullough, Ph.D

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

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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 (the International Federation of Gynecology and Obstetrics) 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 high- and low-resource 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 [1]. In some publications, the phrase "study of" is omitted from the Committee's name.

In 2016, the Committee undertook revision and updating of all statements that appeared in FIGO's 2015 publication, *Ethics in Obstetrics and Gynecology* [2]. Recognizing the international emphasis on professionalism in medicine, in 2018 FIGO leadership approved renaming the Committee to The FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. The title of this collection reflects this name change. Each statement is now termed a "Guideline", followed by a number and the title of the Guideline. Some statements in the 2015 collection are called "guideline" and some are not. The Committee adopted the use of "guideline" to achieve uniformity. This change also brings the statements into line with an essential component of professionalism and an organizational culture of quality and safety: evidence-based guidelines. Ethics and professionalism guidelines should be based on current evidence and on considered judgment that is the product of rigorous ethical reasoning. To reflect this commitment, each guideline after the first presents a background of relevant concepts from professional ethics in obstetrics and gynecology (as explained in Guideline 001). There then follow recommendations based on these concepts, resulting in carefully considered and reasoned practical recommendations.

The *FIGO Ethics and Professionalism Guidelines* are now organized into nine sections. The first section provides a general account of ethics and professionalism in obstetrics and gynecology, which serves as an ethical framework for the guidelines by setting out ethical concepts that shape professional ethics in obstetrics and gynecology. The next section presents guidelines on ethics and professionalism in the physician-patient relationship. The next five sections provide guidelines for daily practice: professionally responsible clinical practice and clinical practice in reproductive medicine, obstetrics, gynecology, and neonatology. Subsequent sections address innovation, research, and scholarship; medical education; and advocacy for women's health policy. A concordance of 2015's *Ethics in Obstetrics and Gynecology* [2] is provided so that readers may link statements from that collection with guidelines in *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. Finally, to support detailed searches of the guidelines, an index is now included.

All of the Ethics and Professionalism Guidelines are available on the FIGO website (https://www.figo.org/committee-ethical-aspects-human-reproduction-andwomens-health) 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 Ethical and Professional Aspects of Human Reproduction and Women's Health. Subject to such acknowledgement, there is no copyright restriction on their use or citation.

# Committee statement to be used when publishing the FIGO Ethics and Professionalism Guidelines:

The FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health provides evidence-based, considered, reasoned judgments about the ethical and professional aspects of Obstetrics, Gynecology, and Women's Health. The FIGO Ethics and Professionalism Guidelines represent the result of carefully researched and rigorous discussion by the Committee. These Guidelines are intended to inform considered judgment about the ethical and professional aspects of obstetrics, gynecology, and women's health by member organizations and their constituent membership.

The Committee revised all statements approved before 2016. This means that the authoritative version of an older statement, now renamed "Guideline," is the Guideline in this edited collection.

# Frank A. Chervenak, M.D., M.M.M, and Laurence B. McCullough, Ph.D., Editors, 2021

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# Committee membership 1997-2000

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# Introduction

It gives me great pleasure to introduce this important volume of **FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology** on behalf of the FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health.

In all aspects of women's health care, ethical concerns need to be addressed and professionally dealt with. Ethical sensitivity in women's health care cannot be overemphasized, as in today's world, still in many countries, communities and religions, and social and family settings, women find themselves in disadvantageous status, if not downright subordinate. In many situations women end up taking a secondary role, even though they sacrifice more, work harder, and are the true support of communities and families. It therefore behooves international organizations like FIGO to deliberate, create, and insist on implementation of ethical guidelines to represent and to protect women, especially when it comes to professional ethics in their health care. In fact, I believe that this should be, and is, the very reason for the existence of FIGO. This was well understood by the FIGO leadership long ago and that is why this Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health was the first special committee set up by the organization.

The present volume is the culmination of five years of work by the Committee that started with the leadership of Prof Frank Chervenak in 2016 and is still an ongoing project. Every aspect of women's health care has been considered by the Committee members over the past 35 years of its existence. As the need arose, newer guidelines were created to benefit the member countries and obstetrician-gynecologists all over the world. *FIGO Ethics and Professionalism Guidelines* 

INTRODUCTION

have already impacted professional and even national decision making in many countries and have benefitted women in improved health care. Over the past five years, every statement was reviewed carefully and updated by the Committee members. The editorial responsibility to gather all the updated and new guidelines in one document was ably borne by Prof Frank Chervenak and Prof Laurence McCullough to bring forward this significant volume for the benefit of FIGO members and their patients. I'd like to recognize the herculean efforts of both editors in putting together this volume in such a succinct manner for everyone to appreciate and use in their everyday dilemmas in ethical issues in women's care. Here I must make mention of Prof Bernard Dickens, a past Chair and many-year member, whose legal brilliance has always helped the Committee to choose every word in a legally correct manner.

As the present Chair of the Committee, I feel privileged to introduce and present this important work of the Committee with immense thanks to the two eminent editors, Prof Frank Chervenak and Prof Laurence McCullough, and to all the past and present Committee members for their contributions.

## **Dr Sanjay Gupte**

MD, DGO, FICOG, LLB, FRCOG

Chair, FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health

# I. Ethics and Professionalism

# Guideline 001: Professionalism in Obstetric and Gynecologic Practice

# Ethics and professional ethics in obstetrics and gynecology

Professional ethics in obstetrics and gynecology is the disciplined study of the morality of obstetrician-gynecologists: the obligations that obstetriciangynecologists have to their patients, to other physicians and healthcare professionals, to healthcare organizations, to insurance companies and governments that pay for patient care, and to society, on the basis of ethical principles and virtues. FIGO is committed to the articulation of a professional ethics of obstetricians and gynecologists that is transcultural, transreligious, and transnational.

# The professional responsibility model

The professional ethics of obstetrics and gynecology can be expressed in the "professional responsibility model." Drawing on evidence-based medicine and the best moral philosophy of their time, the Scottish physician-ethicist, John Gregory (1724–1773), and the English physician-ethicist, Thomas Percival (1740–1804), introduced into the history of medical ethics the ethical concept of the physician as a professional rather than an entrepreneur. This concept requires three commitments of all physicians: (a) competence in clinical practice; (b) primacy of the health-related interests of the patient and the secondary status of self-interest and the interests of third parties to the physician-patient relationship;

and (c) evidence-based medicine as a public trust that exists for the common good rather than the protection of the economic, social, and political power of physicians.

Gregory and Percival meant these three commitments to apply in any cultural context. The ethical concept of medicine as a profession and therefore the professional responsibility model of ethics in obstetrics and gynecology should be understood and implemented as transcultural, transreligious, and transnational.

Clinically competent practice should be based on deliberative clinical judgment, the ethical principle of beneficence and the related concept of medical reasonableness, the ethical principle of respect for autonomy, and the professional virtues. Deliberative clinical judgment is evidence-based, rigorous, transparent, and accountable. The ethical principle of beneficence obligates the physician to identify and provide clinical management that in deliberative clinical judgment is expected to result in net clinical benefit, i.e. a greater balance of clinical goods over clinical harms in the processes and outcomes of patient care. Medical reasonableness is a beneficence-based clinical ethical concept that applies when two criteria are satisfied: clinical management is technically possible and expected to result in net clinical benefit for the patient.

The ethical principle of respect for autonomy obligates the physician to empower the patient to make informed decisions about clinical management of her condition by providing her with an unbiased presentation of information about the medically reasonable alternatives for the management of her condition and the clinical benefits and risks of each medically reasonable alternative and to support her decision making.

The professional virtue of self-effacement calls for the physician to put aside and not be influenced by sources of bias that might distort the commitment to scientific and clinical competence or the commitment to putting the patient's interests first. The professional virtue of self-sacrifice requires the physician to accept reasonable limits on the physician's self-interest in order to fulfill the commitment to putting the patient's interests first, and to accept limits on group self-interest to fulfill the commitment to maintain the profession of medicine as a public trust. The professional virtue of compassion requires the physician to recognize, prevent, and appropriately manage pain, distress, and suffering of patients.

The professional virtue of integrity is key and requires the physician to provide or facilitate clinical care to standards of intellectual and moral excellence. Intellectual excellence requires the physician to provide evidence-based clinical care. Deliberative clinical judgment is essential for improving safety and quality. Moral excellence requires the physician to focus primarily on the protection and promotion of the patient's health-related interests and keep the physician's and group self-interest systematically secondary. Professional integrity prohibits offering, recommending, providing, or referring for clinical management that in deliberative clinical judgment is not expected to result in clinical benefit. Professional integrity also obligates the physician not to provide clinical management that is clinically harmful and to recommend against such clinical management in response to a patient's expression of interest in or request for such treatment. To fulfill this obligation, the physician should explain the evidence base for the deliberative clinical judgment of expected clinical harm and explain that this judgment provides the basis for the recommendation against such harmful clinical management.

# Ethical obligations to patients

Obstetrician-gynecologists have the ethical obligation to ensure that every patient receives clinical management of her condition that is supported in deliberative clinical judgment. An essential component of this obligation is the continuous improvement of the safety and quality of patient care.

Obstetrician-gynecologists should engage patients in decision making that meets the ethical requirements of informed consent. The professional virtue of integrity and the ethical principles of beneficence and respect for autonomy guide this process. The obstetrician-gynecologist's role in the informed decision-making process should not be distant and impersonal but engaged and supportive.

The obstetrician-gynecologist should begin by identifying, on the basis of deliberative clinical judgment, the medically reasonable alternatives for managing the patient's condition. That a form of clinical management is technically possible is not sufficient for considering it to be medically reasonable. There is no ethical obligation to offer such clinical management.

The obstetrician-gynecologist should then present the medically reasonable alternatives to the patient and provide an unbiased description of each alternative along with the clinical benefits and clinical risks of each. This disclosure does not need to include theoretical benefits and risks, which can be distracting. The determination that a form of clinical management is medically reasonable is an expert clinical judgment and therefore not a lay judgment.

There are two clinical contexts in which the obstetrician-gynecologist is ethically justified in making recommendations. The first is when there is only one medically reasonable alternative or when, among two or more medically reasonable alternatives, one is clinically superior in deliberative clinical judgment. Sometimes, among medically reasonable alternatives, no one is clearly superior in deliberative clinical judgment. In such clinical circumstances, the obstetrician-gynecologist should be cautious in making a recommendation and explain the basis for doing so, which may include an unbiased evaluation of the obstetrician-gynecologist's clinical experience. Making ethically justified recommendations is not disrespectful of patient autonomy or inconsistent with shared decision making because such recommendations empower the woman with the valued input of the obstetriciangynecologist's professional clinical judgment.

Obstetrician-gynecologists in leadership positions have the ethical obligation to identify and advocate for the resources required by the commitment to improve the safety and quality of patient care and the informed decision-making process.

# Ethical obligations to other physicians and healthcare professionals

All obstetrician-gynecologists and other healthcare professionals share in professional responsibility for the quality and safety of patient care. The differences among the healthcare professions are a function of the division of labor among healthcare professionals, for example between an obstetriciangynecologist and a midwife. These differences in clinical skill sets should be negotiated on the basis of deliberative clinical judgment. Obstetrician-gynecologists in leadership positions have the professional responsibility to create organizational cultures that support professional collaboration among all members of the healthcare team.

# Ethical obligations to healthcare organizations responsible for patient care

Implementing decisions in patient care draws on the human, material, and financial resources of healthcare organizations responsible for patient care. Obstetrician-gynecologists should use organizational resources on the basis of deliberative clinical judgment. Obstetrician-gynecologists should be aware that the use of resources for one patient can affect access to those resources by another patient. Beneficence and professional integrity create the ethical obligation of obstetrician-gynecologists to prevent what is called an unacceptable opportunity cost: the use of an organizational resource that is not expected in deliberative clinical judgment to benefit a patient when that usage blocks access for a patient who is expected to benefit clinically. For example, the use of the operating room for a non-indicated cesarean delivery may prevent access for a patient who needs an emergent cesarean delivery.

Obstetrician-gynecologists in leadership positions have the ethical obligation to educate their professional colleagues about the concept of unacceptable opportunity costs and to work with their professional colleagues to develop and implement organizational policies and practices designed to prevent the occurrence of and respond rapidly to unacceptable opportunity costs.

# Ethical obligations to insurance companies and governments that pay for patient care

Insurance companies and governments that pay for patient care have an ethical obligation to pay for patient care that is supported in deliberative clinical judgment. Obstetrician-gynecologists have the ethical obligation to document that the clinical management provided was well supported by deliberative clinical judgment. Professional integrity requires that this documentation is accurate and complete.

Obstetrician-gynecologists in leadership positions should work with professional colleagues to ensure that such documentation is routine. Leaders also have the ethical obligation to work with insurance companies and governments to secure payment for clinical management that is supported by well-documented deliberative clinical judgment.

# Ethical obligations to society

Like all physicians and other healthcare professionals, obstetrician-gynecologists have the ethical obligation to society to support the health of the entire population of patients. Obstetrician-gynecologists have the ethical obligation to advocate for women and children.

Obstetrician-gynecologists in leadership positions have the ethical obligation to coordinate advocacy of their professional colleagues for women and children.

# Conclusion

Professionalism is an essential component of obstetric and gynecologic practice. All obstetrician-gynecologists should identify and routinely fulfill their ethical obligations to patients, to other physicians and healthcare professionals, to healthcare organizations, to insurance companies and governments that pay for patient care, and to society, on the basis of ethical principles and professional virtues, as expressed in the professional responsibility model of ethics in obstetrics and gynecology. FIGO is committed to supporting obstetriciangynecologists in their fulfillment of these transcultural, transreligious, and transnational ethical obligations.

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# II. The Physician–Patient Relationship

# Guideline 002: Maintaining Boundaries in the Professional Relationship with Patients

# Background

1. Maintenance of strict boundaries in the professional 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 professional relationship destroys the trust essential to the healthcare and healing process.

# Recommendations

- 1. 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.
- 2. 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.
- 3. Other professional boundary violations that can occur because of the power imbalance include requests for financial advice, benefit, or influence on

decisions outside the healthcare context. All of these have the potential of crossing professional boundaries inappropriately.

4. 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.

# London, July 2016 revision of 1997 version

# Citation for 1997 version:

Report of the Committee for the Study of Ethical Aspects of Human Reproduction. Some ethical issues in the doctor/patient relationship. Patenting of human genes. Ethical aspects in the management of newborn infants at the threshold of viability. The ethical aspects of sexual and reproductive rights. Cloning in human reproduction. *Int J Gynecol Obstet* 1997;59:165–168. PMID: 9431887.

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# **Guideline 003: Decision Making with Patients**

# Background

- 1. Professionally responsible decision making is essential for informing the patient about all medically reasonable alternatives for the clinical management of her condition and the clinical benefits and risks of each such alternative. The goal should be to respect and promote the patient's autonomy.
- 2. It is widely accepted that professionally responsible decision making with patients increases the cooperation of patients with their plan of care, especially when self-care is a major component of that plan.

- 3. Professionally responsible decision making with patients may increase their satisfaction with their clinical care and their relationship with their obstetrician-gynecologist.
- 4. Directive counseling occurs when the obstetrician-gynecologist, following informing the patient about all medically reasonable alternatives, makes a recommendation to the patient based on a deliberative clinical judgment that this course of clinical management will be beneficial to the patient.
- 5. Nondirective counseling occurs when, following informing the patient about all medically reasonable alternatives, the obstetrician-gynecologist offers but does not recommend a medically reasonable alternative to the patient. This is sometimes called "shared decision making." Shared decision making is thought to provide a powerful antidote to physician paternalism (interfering with the patient's autonomy for her clinical benefit). Shared decision making, however, should not be considered a universal model for professionally responsible decision making with the patient.
- 6. Professionally responsible decision making empowers the patient to make informed and voluntary decisions about her clinical care, an essential autonomy-based component of the informed consent process. This includes respect for the woman's decision about whom she wishes to be involved in the decision-making process.
- 7. Professionally responsible decision making protects the patient from clinical harm that can result from poorly informed or uninformed decisions, an essential beneficence-based component of the informed consent process.
- 8. Professionally responsible decision making prevents the obstetriciangynecologist from providing clinical management that is not evidence-based or otherwise not consistent with an accepted professional standard of care, an essential professional-integrity component of the informed consent process.
- Directive counseling is professionally responsible when there is only one medically reasonable alternative to no treatment or when the evidence is clear that among two or more medically reasonable alternatives one is clinically superior.
- 10. Nondirective counseling is professionally responsible when there is more than one medically reasonable alternative and when the evidence is not clear that one among these medically reasonable alternatives is clinically superior.

# Recommendations

- 1. The obstetrician-gynecologist fulfils the requirements of a professionally responsible informed consent process in the following steps:
  - a. Provide the patient with a reliable account of her present condition, its causes, and its prognosis with and without treatment;
  - b. Provide the patient with an accessible description of all medically reasonable alternatives and the evidence base for each;
  - c. Provide the patient with an accessible description of the clinical benefits and risks of each medically reasonable alternative;
  - d. Engage in directive counseling when it is justified: recommend a medically reasonable alternative because it is the only one (compared to no treatment) or is supported by evidence to be clinically superior;
  - e. Otherwise, engage in nondirective counseling: offer but do not recommend the medically reasonable alternatives;
  - f. Offer to assist the patient to assess what has been recommended or offered, on the basis of her interpretation of what she has been told and on the basis of her values and beliefs;
  - g. Make a reasonable effort to detect and mitigate potentially controlling influences, to support voluntary decision making;
  - h. Elicit her authorization of a medically reasonable alternative;
  - i. Elicit and address any remaining questions or concerns that the patient may have.
- 2. In shared decision making, some patients may authorize a medically reasonable alternative, rejecting others that the obstetrician-gynecologist might prefer. It is consistent with professional responsibility to provide the course of clinical management authorized by the patient.
- Some patients may refuse to authorize all medically reasonable alternatives. The obstetrician-gynecologist fulfils the requirements of a professionally responsible informed refusal process in the following steps:
  - a. Explain the clinical risks to the patient or the risks to her unborn child, if relevant, of implementing her refusal and documenting this disclosure in detail in her record. Applicable legal requirements should be satisfied.
  - b. Assume she has a good reason for refusing and document the reasons why she is refusing.
  - c. If she expresses values that support a medically reasonable alternative, ask her to reconsider. If she agrees, then implement her authorization.If she does not agree and directive counseling is justified, repeat the

recommendation and express concern about her health or that of her unborn child, if relevant. With the patient's permission, involving other healthcare professionals, or others identified by the patient, may be helpful.

- d. Be attentive to influences that may have resulted in involuntary refusal. Respectfully isolate the influences from the patient and ask her to reconsider.
- e. Consider whether the patient is exhibiting impaired decision-making capacity: paying attention, retaining and using information; understanding consequences of nontreatment (cognitive understanding); believing those consequences could happen to her (appreciation); and evaluating those consequences (evaluative understanding). If formal evaluation is reasonable, seek consultation from a qualified and experienced psychiatrist or psychologist.
- For patients who have been reliably judged to irreversibly lack the capacity to engage in the informed consent process, utilize surrogate decision making. Where there is legal guidance for surrogate decision making, it should be followed.

# Additional readings

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Patients' refusal of recommended treatment. *Int J Obstet Gynecol* 2015; 128:280–281.

Dickens BM, Cook RJ. Patients' refusal of recommended treatment. *Int J Obstet Gynecol* 2015;131:105–108.

Chervenak FA, McCullough LB. The unlimited rights-based model of obstetric ethics threatens professionalism. *BJOG* 2017;124:1144–1147.

# London, July 2017 (new)

# Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 003: Decision making with patients. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 16–19.

# **Guideline 004: Informed Consent**

# Background

- 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 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), the UNESCO Declaration on Bioethics and Human Rights (article 6) 2005, and the World Health Organization (WHO) (2017).
- 2. The following definition of informed consent [1] flows from these human rights and is endorsed by the FIGO Committee for the Study of Ethics and Professionalism in 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.

Providing this information is essential for empowering women to make decisions with their physicians, as required by the ethical principle of respect for patient autonomy. There are no valid conscience-based objections to the ethical obligation to provide this information.

# Recommendations

- 1. 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 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 ensuring that the process of communication is satisfactory before informed consent occurs. This means that others may become involved in her decision-making process only with her explicit permission.
- 2. Consent can be withdrawn at any time. The patient should be informed about the risks of discontinuation of treatment and how these should be managed.
- 3. It is important to keep in mind that informed consent is not a signature, but a process of communication and interaction. The signed consent form documents only that the patient has authorized treatment.
- 4. The opinion of children or adolescents on a medical intervention should be assessed within the limitations posed by their level of development or understanding. This is known as pediatric assent. The more mature the adolescent's decision-making process, the greater the ethical weight that should be given to her decisions by her physician and by her parents. Applicable law may recognize the adolescent's decision-making authority over herself.
- 5. Even if a woman is unable to decide for herself because of mental incapacity or intellectual disability, 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 by her joint decision maker.

## References

[1] UN Resolution on Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care 11.2. https://www.who.int/mental\_health/policy/en/UN\_Resolution\_on\_protection\_of\_persons\_with\_mental\_illness.pdf

# London, July 2018 revision of 2007 version

## Citation for 2007 version:

Milliez J; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Guidelines regarding informed consent. *Int J Gynecol Obstet.* 2008;101:219–220. doi: 10.1016/j.ijgo.2008.02.002. PMID: 18358476.

# Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 004: Informed consent. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 20–22.

# Guideline 005: Confidentiality

# Background

1. Two intertwined concepts, confidentiality and privacy, are critically important to the sensitive issues addressed in the course of health care for women. Confidentiality is the professional responsibility to protect health information about a patient from unauthorized access by others. Privacy creates a zone of decision making and behavior into which others, especially the state, may not enter without compelling reasons. 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 coincides with the professional obligation of confidentiality, particularly in environments with computer access to patient records.

- 2. Women are particularly vulnerable to personal harm or discrimination from breaches in confidentiality, particularly in those circumstances where domestic violence or testing for infectious diseases or genetic disorders is involved. Because of their greater risks from breaches in confidentiality, the obligation to ensure confidentiality in women's health care should be strictly observed.
- 3. Modern principles of data protection have been recognized 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
  - stored data should be adequate, relevant, and not excessive
  - data is available to the patient to verify factual accuracy
  - data is processed fairly and lawfully
  - data is not stored for longer than will serve the interests of the patient or patients, and
  - 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.
- 4. Continuity of information protected by confidentiality is essential for continuity of care, especially when the patient is attended by multiple physicians and other healthcare professionals. Medical information protected by confidentiality is also essential for improvement of healthcare services, public health, and the advancement of research in health care. Sharing information with a parent, guardian, or other surrogate decision maker can raise special concerns for confidentiality. Furthermore, when information regarding a person's health has serious implications for the health of others, the question arises as to whether or not the health professional should break the professional obligation of confidentiality in order to prevent serious, farreaching, and irreversible harm to others.
- 5. Competent patients have the right of access to information in their medical records, to have the data interpreted for them, and to have their objection to the inclusion of specific information included in their record. Patients also have the right to correct inaccurate factual information in their records.
- 6. 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.

7. 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 use of information remains under the control of the identified patient. Medical personnel and facilities are trustees of the information, bound by ethical duties of professionally responsible patient care.

# Recommendations

- Obstetrician-gynecologists and their staffs have the professional responsibility to maintain confidentiality of health information about patients. The patient's right to confidentiality derives from this professional responsibility.
- 2. Patients also have privacy-based rights that are respected when the professional responsibility of confidentiality is fulfilled.
- 3. Obstetrician-gynecologists and health facilities should ensure that data stored about patients is accurate, complete, not excessive to the purpose of storage, and protected from unauthorized access.
- 4. 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.
- 5. Every obstetrician-gynecologist is obligated to maintain confidentiality of health information in all settings, including informal settings (e.g. hallway conversations, and in elevators, social settings, publications, and lectures).
- 6. 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 obstetrician-gynecologist additionally should advocate for continual improvement of security of electronic records systems.
- 7. When the health of a patient has serious and harmful implications for the health of others, the obstetrician-gynecologist 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 lifethreatening harm to a specific individual, the physician has an obligation to report the risk appropriately.

- 8. Parents, guardians, and surrogate decision makers have the right to be provided with information necessary for informed decision making about the patient's care. The obstetrician-gynecologist should impress on these decision makers their responsibility to protect the patient's privacy by not sharing this information with others.
- 9. However, the developing growth of the pediatric patient'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 obstetrician-gynecologist should inform parents that the patient may make decisions to withhold information from the family. To the extent practicable, the physician should maintain confidentiality, especially when revealing information may directly lead to serious harm to the child.
- 10. 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 or the patient's authorized representative.
- 11. Healthcare information should be available for medical research and healthcare system improvement, provided it is securely de-identified.
- 12. Many circumstances surrounding an otherwise confidential medical encounter can endanger confidentiality. The title of a clinic, the letterhead on a patient letter, the color 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 an obstetrician-gynecologist does not have a patient–physician relationship, any medical information the physician receives regarding a patient must still be held in strict confidence.

# London, July 2017 revision of 2005 version

## Citation for 2005 version:

FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women's Health. Confidentiality, privacy and security of patients' health care information. *Int J Gynecol Obstet* 2006;93:184–186. doi: 10.1016/j.ijgo.2006.03.011. PMID: 16603162.

# Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 005: Confidentiality. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 22–26.

# **Guideline 006: Confidentiality and Adolescent Patients**

# 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, 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 concerning the health services that are requested and provided. There is also a beneficence-based professional responsibility to maintain patient confidentiality, by preventing unauthorized access to patients' records and conversations with patients. 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 unwanted pregnancy. Adhering to the rights-based and professional-ethics-based ethical obligation of confidentiality can allay these fears.

- 4. The UN Convention on the Rights of the Child [1] recognizes 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." This is known as pediatric assent, the capacity of the adolescent patient to participate in decision making in a developmentally appropriate way. Confidentiality protects and promotes pediatric assent.
- 5. Assessments of young persons' capacity may involve consultation with other medical and related professionals, under 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."
- Pregnancy is a leading cause of death worldwide among women aged 15 to 19 years, 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 confidentiality that is consistent with their evolving capacity to make decisions in their own lives.

# Recommendations

1. Healthcare providers should recognize that adolescents and youths can possess capacity to make substantial life choices for themselves in a developmentally appropriate way. 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. The more adult-like the patient's capacity, the stronger her rights of decision making become.

- 2. Adolescents 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 protected, consistent with applicable law and health policy.
- 3. National societies and obstetrician-gynecologists should urge reform of laws and policies that restrict young persons' access to reproductive health care, and work with governments, politicians, and other organizations, for instance, nongovernmental 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 and concerns that parents might not be supportive should be taken seriously and appropriate assistance offered.
- 5. Care should be provided nonjudgmentally. It is consistent with such an approach that practitioners and/or counselors advise their patients about the disadvantages of premature sexual relations, including risks of STIs such as HIV/AIDS and the risks of unwanted sexual activity and exploitation, especially when the male partner is older. 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 helpline or confidential website 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.
#### References

[1] UN General Assembly. Convention on the Rights of the Child. 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3. https://www.ohchr.org/en/professionalinterest/pages/crc.aspx. Accessed June 21, 2021.

#### London, July 2018 revision of 2008 version

#### Citation for 2008 version:

Milliez J. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Adolescent and youth reproductive health care and confidentiality. *Int J Gynecol Obstet* 2009;106:271–272. doi: 10.1016/j.ijgo.2009.03.049. PMID: 19394615.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 006: Confidentiality and adolescent patients. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 26–29.

# Guideline 007: Disclosing Adverse Outcomes of Medical Care

- 1. 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. These errors should be addressed by organizational leadership with the goal of changing policies and practices to prevent errors.
- 2. When a physician is responsible for the error, he or she has 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 and therefore should be taught. 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.

- 3. 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 have autonomy and make choices for their own health care. Without an understanding of their healthcare circumstances, they cannot make informed decisions for their own care within their own framework of values and needs.
- 4. 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.

- 1. The goals of such a discussion are to tell patients and/or families as appropriate about an untoward outcome in a timely fashion and the clinical plan for its management and prevention, to ensure continuing communication and explain whether and when 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.
- 2. The explanations should include the nature of the event as well as the short-term and long-term health consequences.
- 3. The individual communicating with the patient should be the physician responsible for the adverse event. This professional responsibility should not be transferred to others on the healthcare team such as junior physicians, nurses, or trainees.
- 4. It is important to tell patients and/or families that the physician or healthcare team regrets that this has happened to them, and is committed to see what can be done to alleviate any problems resulting from the event and to determine how to ensure that it does not happen to someone else. Making a personal apology may increase risk of professional liability. Organizational policy should make clear the form that an apology should take and how it should be documented in the patient's record. 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.

- 5. Physicians and other healthcare professionals have the professional responsibility to advocate for and maintain standards of patient safety and quality, as an essential component of preventing adverse events.
- 6. 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, July 2018 revision of 2010 version

#### Citation for 2010 version:

Dickens B. Disclosing adverse outcomes in medical care. *Int J Gynecol Obstet* 2010;111:192. doi: 10.1016/j.ijgo.2010.07.006. PMID: 20801443.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 007: Disclosing adverse outcomes of medical care. In Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 29–31.

## **Guideline 008: Patients' Refusal of Recommended Treatment**

- Treatment that has significant clinical risks may ethically be provided to patients only with their informed consent. It follows that if a patient refuses to consent to recommended treatments, such treatments usually cannot ethically be imposed upon her. The clinical management of patients' refusals of recommended treatment raises ethical concerns regarding informed refusal, patients' mental and legal capacity to make their decisions, how to respond to refusals, 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. 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 necessary care.

- 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. In law, imposing treatment contrary to patients' refusals, whatever their basis, is likely to constitute 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 empower informed decisions. Patients may freely decline this offer and consent to recommended treatments by trusting their physicians' recommendations. If they refuse indicated treatment recommended to them in their best interests, however, the obstetrician-gynecologist 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. This is known as informed refusal. In some jurisdictions, informed refusal is a legal obligation and this should be documented in the patient's record.
- 6. Patients who refuse recommended treatments but voluntarily maintain their doctor-patient relationships cannot be abandoned. Instead, the obstetrician-gynecologist should explore the patient's reasons and, when her reasons support what has been recommended, this should be pointed out to the patient and she should be asked to reconsider. This is known as respectful persuasion. 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 delivery and for whom respectful persuasion fails should be assisted in vaginal delivery. Healthcare professionals commit no ethical or legal breach in acquiescing to informed patients' freely chosen refusals of recommended care, even when patients' lives are in peril. Organizational policy should identify how the obstetrician-gynecologist should respond to refusal of recommended clinical management.

- 7. Patients' refusals of recommended treatments may raise issues of patients' decision-making capacity. The fact that a patient has refused recommended clinical management does not by itself establish that the patient has impaired decision-making capacity. Impairments of the ability to pay attention, to absorb and retain information, to reason from present events to their clinical outcomes (cognitive understanding), to believe that these outcomes could happen to her (appreciation), and to assess outcomes on the basis of her values and beliefs (evaluative understanding) generate the hypothesis that the patient is experiencing impaired decision-making capacity. Each of these components of decision-making capacity should be assessed. If impairments are clinically reversible, a plan for doing so should be presented to the patient. If impairments are not clinically reversible, surrogate decision making is required.
- 8. There are two ethical standards for surrogate decision making, which are also legal standards in some jurisdictions. The first is the substituted judgment standard, according to which the surrogate should base decisions on the patient's values and beliefs when these can be reliably identified. When this is not the case, the surrogate should follow the best interests standard, which is based on a comprehensive assessment of the patient's health-related interests.
- 9. Mature adolescents' refusals cannot ethically be overridden by parental authority (see Guideline 006: Confidentiality and Adolescent Patients).
- 10. An exception to the informed consent requirements above is emergency situations where consent cannot be obtained from or on behalf of the patient because of the time constraint of needing to initiate clinical management immediately. Another exception is court authorization of treatment. Organizational policy should provide clear direction for how to manage these exceptions.

#### Recommendations

- 1. The obstetrician-gynecologist should explain to each patient the nature and purpose of recommended treatments to empower informed decision making.
- 2. When a patient refuses recommended treatment, the obstetriciangynecologist should respond first with respectful persuasion. When respectful persuasion fails, the informed refusal process should be followed and appropriately documented.
- 3. The obstetrician-gynecologist should not presume that a patient's refusal of recommended treatment is due to impairments of the patient's decision-making capacity.
- 4. Intellectually mature minors' informed consent to or refusal of recommended treatments should not be allowed to be overridden by parents' or guardians' preferences. When parents have legal decision-making authority over a minor patient, the obstetrician-gynecologist should support the parents in respecting the patient's informed decisions.
- 5. When a patient exhibits impairment of one or more components of decisionmaking capacity, these should be assessed. The goal should be to provide interventions to reverse impairments.
- 6. When such interventions fail, surrogate decision making should be used. The surrogate should first attempt to fulfill the substituted judgment standard. If this attempt fails, the surrogate should attempt to fulfill the best interests standard.
- 7. Organizational policy should provide a process for identifying the surrogate decision maker. Such policy should be based on existing, applicable law.
- 8. No third party should be allowed to refuse administration of necessary treatment to which a patient with decision-making capacity has consented.

#### London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Patients' refusal of recommended treatment. *Int J Gynecol Obstet* 2015;128:280–281. doi: 10.1016/j.ijgo.2014.10.009. PMID: 25458414.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 008: Patients' refusal of recommended treatment. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 31–34.

## **Guideline 009: Treating Family Members and Close Friends**

- 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. Family members and close friends may have more trust and confidence in physicians they know than in other physicians.
- 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 failure to meet accepted professional standards that support the objective appraisal necessary in a professional relationship and prevent personal bias.
- 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 professional, are generally ethically not problematic, because acting in the professional role is not necessary.
- 4. In the case of potentially more serious conditions, however, the boundaries between physicians' personal and professional relationships can become blurred and thereby introduce a potential for conflict of commitment and failure to meet accepted professional standards of clinical care. Therapeutic treatment is acceptable only in an emergency, until recipients are transferred to independent care. The same restraint governs physicians' self-medication.
- 5. Concerns are especially acute for obstetrician-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 clinically indicated second opinions.
- 6. Informal discussions among family members and close friends are not governed by the professional obligation of confidentiality that applies in

medical professional relationships. 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.

- 7. Obstetrician-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 Guideline 006: Confidentiality and adolescent patients.
- 8. Preventable professional liability issues arise when 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.
- 9. Professional services are ethically and legally expected to conform to professional standards 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.
- 10. 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

 Providing clinical care to family members and close friends is at risk for preventable conflict of commitment that can result from blurring boundaries between professional responsibility and one's responsibility as a family member or friend. The burden of proof, therefore, is on the obstetriciangynecologist who elects to provide clinical care to family members or close friends.

- 2. The commitment to professional obligations should supersede the commitment to personal relationships when family members or friends request or require nonemergency clinical management of their conditions. To prevent unnecessary and potentially unmanageable conflicts of commitment and thereby protect the health-related interests of patients, obstetriciangynecologists should maintain a clear boundary between professional and personal relationships.
- 3. Family members or close friends who request or need nonemergency professional management of their conditions should be referred to the appropriate physician.

#### London, July 2019 revision of 2015 version

#### Citation for 2015 version:

Dickens B; FIGO Committee for The Ethical Aspects of Human Reproduction and Women's Health. Ethical issues in treating family members and close friends. *Int J Gynecol Obstet* 2016;133:247–248. doi: 10.1016/j.ijgo.2016.02.002. PMID: 26952347.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 009: Treating family members and close friends. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 35–37.

# III. Professionally Responsible Clinical Practice

# Guideline 010: Conflicts of Interest, Appearances of Conflicts of Interest, and Conflicts of Commitment for FIGO Leadership

#### Background

The International Federation of Gynecology and Obstetrics (FIGO) is 1. an organization that consists of 130 national obstetric and gynecologic societies. As such, the actions of its staff, committees, working groups, officers, and Executive Board can have significant impact upon patients, its members, and industry throughout the world. As a charitable organization incorporated in the United Kingdom (UK), actions by FIGO and any official person or body of FIGO can be and is subject to public scrutiny in the UK as well as the countries of its member societies. To avoid any appearance that the staff, committees, working groups, officers, or Executive Board Members have inappropriately benefited from any FIGO action, it is imperative that FIGO has a policy that establishes guidelines and procedures that will offer protection against claims of impropriety and gives involved members a mechanism for recognition; this policy must contain a process for the affected party (or parties) to have a fair, impartial evaluation of any such claim. There should also be established procedures in which individuals with a conflict of interest can be excused from voting or other activities associated with the conflict of interest.

2. Since FIGO is recognized as the international organization to which 130 national associations belong, it is also important that each of these organizations develop their own Conflict of Interest Policy. In the absence of a local policy, the national associations are free to utilize the FIGO Policy as their own. The FIGO Policy may also be amended or otherwise altered to meet the individual needs of the national society but may not then be referred to as the FIGO Conflict of Interest Policy. The scope of this policy is limited to financial conflicts of interest.

#### Definitions

- 1. **Organizational conflict of interest.** An organizational conflict of interest exists when the financial self-interests of an individual associated with the organization are at odds with the obligation of that individual to the organization to further its mission and charitable purpose. This circumstance can arise due to a range of activities and includes obligations to a donor; development of guidelines favoring a sponsor who provides financial support; using one's name or position in the organization to receive personal benefit from endorsement; referring contracts of the organization to a company or organization where the referring individual has a financial interest.
- 2. **Appearance of conflict of interest**. An appearance of conflict of interest can also occur. This happens when an individual in an organization has a relationship with an outside company that could be perceived as creating a conflict of interest.
- 3. **Conflict of commitment**. A conflict of commitment occurs when an individual has an obligation to more than one organization. This might result in divided loyalties.
- 4. **Professional integrity**. Professional integrity requires FIGO leaders and staff members to maintain professional standards and values from erosion from biasing self-interest.

- In order to sustain the professional integrity of FIGO and its members, all conflicts of interest, appearances of conflicts of interest, and conflicts of commitment of FIGO leadership and staff must be responsibly managed. FIGO herewith adopts a three-component management policy:
  - a. Mandatory disclosure by FIGO leadership (officers, board members, committee chairs) and staff to the FIGO Professional Integrity Advisory Committee.

- b. Evaluation by the Professional Integrity Advisory Committee.
- c. Management plan recommended by the Professional Integrity Advisory Committee to the FIGO Board.
- 2. The FIGO Professional Integrity Advisory Committee should be charged by the Board to prepare a document detailing these three components for review and approval by the Board.

#### Additional readings

Council of Medical Specialty Societies. Code for Interaction with companies. April 2015. https://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations.pdf. Accessed July 28, 2017.

Fineburg HV. Conflict of interest. Why does it matter? JAMA 2017;317:1717-1718.

Rothman DJ, McDonald WJ, Berkowitz CD, et al. Professional medical associations and their relationships with industry: a proposal for controlling conflicts of interest. *JAMA* 2009;301:1367–1372.

#### London, 2017 (new)

#### Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 010: Conflicts of interest, appearances of conflict of interest, and conflicts of commitment for FIGO leadership. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 38–40.

# Guideline 011: Conflicts of Interest in Clinical Practice and Research

#### Background

 Obstetrician-gynecologists confront conflicts of interest in clinical practice and research. Every obstetrician-gynecologist has the professional responsibility to manage these conflicts on the basis of the professional virtue of integrity.

## Definitions

- 1. **Conflict of interest.** A conflict of interest exists when an obstetriciangynecologist or his or her family member (spouse, children, trusts) selfinterests are at odds with that individual's obligation to patients or research subjects. This occurs when self-interest has the potential to bias clinical judgment and practice. These biasing self-interests may be financial or nonfinancial.
- 2. **Professional integrity**. Professional integrity requires the obstetriciangynecologists to maintain professional standards and values from erosion from biasing self-interest. This is accomplished by evidence-based reasoning, to minimize bias in clinical judgment, and by transparency about conflicts of interest.

## Recommendations

The Committee recommends the following to professionally manage conflicts of interest.

- 1. The preferred management of conflicts of interest is to avoid them when they are unnecessary.
- 2. For unavoidable conflicts of interest:
  - a. Minimize the potential for bias by minimizing the biasing effect of the conflict of interest.
  - b. Routinely disclose conflicts of interest to patients and explain how they have been minimized to protect professional integrity and therefore protect the patient.
  - c. Respect the patient's decision about whether to proceed with patient care or referral to a clinical trial.

#### Additional readings

Council of Medical Specialty Societies. Code for Interaction with companies. April 2015. https://cmss.org/wp-content/uploads/2016/02/CMSS-Code-for-Interactions-with-Companies-Approved-Revised-Version-4.13.15-with-Annotations.pdf. Accessed July 28, 2017.

Fineburg HV. Conflict of interest. Why does it matter? JAMA 2017;317:1717-1718.

Rothman DJ, McDonald WJ, Berkowitz CD, et al. Professional medical associations and their relationships with industry: a proposal for controlling conflicts of interest. *JAMA* 2009;301:1367–1372.

#### London, 2017 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Recommendations on conflict of interest, including relationships with industry. *Int J Gynecol Obstet* 2015;128:282–283. doi: 10.1016/j.ijgo.2014.10.010. PMID: 25458415.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 011: Responsibly managing conflicts of interest in clinical practice and research. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 40–42.

# Guideline 012: Helping Patients Access Medical Information on the World Wide Web

- 1. 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-reviewed 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 recognized 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 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.
- 2. 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 nonvalidated information, in order to support their own views, interests, beliefs, propaganda, or philosophy. In

addition, influential medical authorities may share these views and provide endorsement for these points of view even though the evidence and quality of research are lacking. These inherent biases are not identified, and the reader's ability to identify the fact that this is, in reality, lobbying for a point of view rather than sharing medical facts in an unbiased fashion may be limited. Patients need to be able to discriminate between lobbying, which is meant for the initiating group's benefit, and information that is designed for the sake of public education.

#### Recommendations

- To protect the integrity of the patient's decision-making process about clinical care, the obstetrician-gynecologist has the professional responsibility to assist patients in accessing scientifically and clinically reliable information on the World Wide Web. To achieve this goal, the obstetrician-gynecologist should recommend that the patient visit sites that are known for such reliability, such as those maintained by FIGO and national professional associations of obstetrician-gynecologists.
- 2. The obstetrician-gynecologist should emphasize that visiting other sites runs the risk of accessing inaccurate information that the patient would not know is inaccurate.

#### London, July 2017 revision of 2003 version

#### Citation for 2003 version:

FIGO Committee for the Ethical Aspects of Reproductive Medicine and Women's Health. Recommendations for medical information and advertising on the web. In: *Ethical Issues in Obstetrics and Gynecology*. London: FIGO; 2015:138–140.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 012: Helping patients access medical information on the world wide web. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 42–43.

# Guideline 013: Advertising

#### Background

- Advertising in all forms of media and communication is focused on personal or institutional benefit in a competitive marketplace for the services of obstetrician-gynecologists. Hospitals, health institutions, and professional practice groups are free to promote services and describe services available. However, the quality of those services and the limits of availability of services are rarely critically identified, leading to a biased and potentially harmful choice by patients if they should seek care that is not available or is of questionable quality based on this advertising approach.
- 2. Advertising healthcare services by obstetrician-gynecologists should be understood as part of the disclosure component of the informed consent process. Advertising is therefore governed by the professional ethics of informed consent. This requires veracity of claims in the content of advertising, including description of services and their outcomes and the qualifications of obstetrician-gynecologists and other healthcare professionals in providing those services.

- 1. Obstetrician-gynecologists should take professional responsibility for the validity of the claims made in advertising by healthcare organizations or by their healthcare organizations that market an obstetrician-gynecologist's services. Bias in presentation of information to patients is not consistent with the professional ethics of informed consent and not consistent with the professional ethics of advertising. The scope of this professional responsibility includes provision of accurate and verifiable information about education, training, certification, and licensure.
- 2. The professional ethics of advertising by healthcare organizations requires them to provide direct oversight of advertising to ensure its accuracy and veracity in all respects, to eliminate the introduction of bias in the informed decisions of patients who seek care from a healthcare organization.

#### London, July 2017 revision of 2003 version

#### Citation for 2003 version:

FIGO Committee for the Ethical Aspects of Reproductive Medicine and Women's Health. Recommendations for medical information and advertising on the web. In: *Ethical Issues in Obstetrics and Gynecology*. London: FIGO; 2015: 138–140.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 013: Advertising. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 44–45.

# **Guideline 014: Conscientious Objection**

- 1. The primary commitment of obstetrician-gynecologists is to serve women's reproductive health and well-being. Obstetrician-gynecologists who find themselves unable to deliver care to their patients for reasons of their personal conscience still have professional responsibilities to them. When practitioners consider themselves for good reason to be obliged to place their personal conscientious commitments before the fulfillment of professional responsibility, they have a conflict of commitment. Because patients seek care from professionals and not private individuals, the burden of justification is on the obstetrician-gynecologist who believes that personal commitments should take precedence over professional responsibility in patient care.
- 2. It is unethical for an obstetrician-gynecologist not to fulfill the professional responsibility to inform all patients of all medically reasonable alternatives for their care in an evidence-based and unbiased fashion, including alternatives that an obstetrician-gynecologist is unwilling as a matter of conscience to provide.
- 3. All obstetrician-gynecologists have the professional responsibility to see to it that every patient receives the clinical care she has authorized in the informed consent process. When an obstetrician-gynecologist has a

conscience-based objection to providing a medically reasonable alternative, the obstetrician-gynecologist should refer the patient to a qualified colleague who does not have such an objection.

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 nonobjecting 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.

- 1. All obstetrician-gynecologists have the professional responsibility to see to it that all of their patients receive clinical management to which the patient has consented. All conscientious objections to treating a patient are secondary to this professional responsibility.
- 2. Provision of benefit and prevention of harm require that practitioners provide such patients with timely access to medical services, including giving information about all medically reasonable alternatives for their care, including any such procedures in which an obstetrician-gynecologist objects to providing on grounds of conscience.
- 3. All obstetrician-gynecologists have the professional responsibility 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. Obstetrician-gynecologists have a right to be respected for their conscientious convictions, when these are genuine and clearly expressed. Politically motivated or financially motivated assertions of "conscience" are egregiously unethical. Obstetrician-gynecologists who express conscience-based convictions that are genuine should not suffer discrimination on the basis of their convictions, provided that the obstetrician-gynecologist fulfills the professional responsibility to see to it that the patient receives the clinical management that the patient has authorized.
- 5. There is a professional responsibility to refer patients for medically indicated clinical management, to which an obstetrician-gynecologist objects to undertaking, to qualified physicians who do not object. Referral for services does not constitute participation in any procedures agreed upon between patients and the physicians to whom they are referred, because that care will

be authorized by the patient consenting to what another physician offers to the patient.

- 6. Obstetrician-gynecologists must provide timely referral of their patients when delay would jeopardize patients' life, health, and well-being, such as by patients experiencing unwanted pregnancy.
- 7. In emergency situations, to preserve life or physical or mental health, obstetrician-gynecologists must provide the medically indicated care of their patients' choice regardless of the practitioners' personal objections.

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on conscientious objection. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2006;92:333–334. doi: 10.1016/j.ijgo.2005.12.020.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 014: Conscientious objection. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology.* London: FIGO; 2021: 45–47.

# Guideline 015: Harmful Stereotyping of Women in Health Care

#### Background

1. The United Nations' Convention on the Elimination of All Forms of Discrimination against Women [1], 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 generalized, often factually incorrect, view or preconception of superiority or inferiority of attributes possessed by a population group with which an individual is identified. Stereotypes presume how that individual, because of ascribed membership in that group, feels, is able to act, and wants to act, without regard to that individual's personal disposition, capacities, qualities, or autonomy. 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 in all cultures. 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 professionals 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 ("breadwinners") in their families; and they will be subordinate to men such as fathers, husbands, brothers, co-employees, and male healthcare professionals. Comparably demeaning stereotypes are that unmarried women seeking contraception are promiscuous and that women willing to serve as surrogate mothers have mercenary motives.
- 5. Laws may reinforce the stereotypes of women as dependents and subordinates. Where males legally control and/or are primary contributors to family resources and make payments for health services and/or insurance, male family members may have to be asked to approve women's care. This reduces women's rights to independent decision making. Such males' legal authorization has to be adequately informed of the dependent women's medical circumstances, so that the professional obligation to maintain the patient's confidentiality is not compromised, further reducing women's rights to self-determination.

- 6. In hospitals and comparable healthcare facilities, obstetrician-gynecologists 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 recognized as independent of the control of physicians, the profession of nursing still struggles in many geographic and practice areas to be acknowledged as independent of physicians' control of performance standards.
- 7. Some of the harms that have resulted from stereotypical attitudes include pregnant women being denied treatments and disclosure of available treatments that are medically indicated for care of pregnancy-unrelated conditions, such as cardiovascular disease and cancers, because such treatments may compromise fetal survival or well-being. The stereotypical presumption is that the general inclination of women is to be self-sacrificing mothers-to-be who would always place fetal interests above their own. This stereotype falsely assumes that there are no ethically justified limits on the ethical obligations to her fetus and future child. Acting on such stereotypes denies pregnant women the right to balance the competing responsibilities in their individual lives according to their personal preferences and assessments. The stereotype of women's vulnerability and emotionalism may lead a healthcare professional to withhold information necessary for a woman's informed consent because it may be distressing or could provoke anxiety.
- 8. A stereotype is being actively promoted in the contested area of abortion, where laws are becoming progressively liberalized, rejecting claims that fetal interests are inherently superior to those of pregnant women. 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 female healthcare professionals, especially female physicians and nurses, by senior medical staff. A particular concern is sexual harassment of junior staff. This reflects the history of ethically impermissible sexual abuse of female patients by male healthcare professionals, at every level of authority. Beyond abuse are stereotypical assumptions that female doctors will specialize in women's health concerns, such as reproductive health, pediatrics, and psychosocial care, and will provide empathetic emotional support for patients, of both sexes, not expected of male physicians.

- Professional integrity creates an ethical obligation to adhere to the accepted standards of evidence-based clinical judgment and practice. Healthcare professionals should therefore offer or recommend care only when they know their patients as the individuals they are, not simply as "types of patients." Patients' presenting conditions and superficial appearances must not be taken to define them as members of a general category of persons.
- 2. Healthcare professionals caring for female and pregnant 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 professionals should ensure that negative stereotyping of female colleagues and subordinates is avoided.
- 4. Healthcare professionals 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 nonjudgmentally, 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.

- Healthcare professionals must be vigilant to recognize and redress their own tendencies to approach female and pregnant patients, prospective patients, colleagues, and others through restrictive or negative stereotypes. Obstetrician-gynecologists should promote women's dignity and rights to pursue self-fulfillment equally with that of men.
- 6. Healthcare professionals 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.

#### Reference

[1] UN General Assembly. The convention on the elimination of all forms of discrimination against women. https://www.un.org/womenwatch/daw/cedaw/. Accessed June 22, 2021.

#### London, July 2019 revision of 2011 version

#### Citation for 2011 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Harmful stereotyping of women in health care. *Int J Gynecol Obstet* 2011;115:90–91. doi: 10.1016/j.ijgo.2011.07.005. PMID: 21839451.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 015: Harmful stereotyping of women in health care. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 41–51.

# Guideline 081: Responsibly Managing Clinical Variation to Improve Quality

#### Background

 The concept of quality in health care is complex. One of its key concepts, wide variation in a production or service process, originated in the globally influential management philosophy of W. Edwards Deming (1900–1993) [1]. Wide variation occurs in patient care when the processes of patient care vary for idiosyncratic reasons, e.g. when hysterectomy rates, adjusted for acuity, differ between hospitals or between physicians in a hospital. Because wide idiosyncratic clinical variation can have adverse outcomes, such variation is part of the definition of poor-quality patient care. Processes of patient care in which variation has been responsibly managed to a minimum is one component of high-quality patient care.

- 2. Uncontrolled variation is clinically significant. It can result in either overtreatment or undertreatment. It can also result in medical errors (doing the wrong thing or doing the right thing the wrong way).
- 3. The replacement of uncontrolled variation with responsibly managed variation in the processes of patient care is an effective way to manage the costs of obstetric and gynecologic patient care.
- 4. The improvement of the quality of the processes of patient care should be undertaken by an interdisciplinary team that includes expertise in obstetrics and gynecology, nursing, organizational management and leadership, and other disciplinary expertise as needed.
- 5. This team should begin by identifying components of patient care displaying the widest variation. The team should then identify their cause, design an intervention to alter the cause with the goal of reducing the variation, identify whether variation has been reduced, the outcomes, and determine whether the new outcome prevents overtreatment, undertreatment, or medical errors. This process should be repeated until no component of the process of the patient care displays wide variation. Remaining variation, provided that it is well managed, is acceptable and should be monitored to prevent recurrence of wide variation.

For example, a group of gynecologists may have the highest rate of hysterectomy for pelvic pain in a hospital with multiple gynecologic groups in a hospital. The chair of the department becomes aware of organizational data that do not show improved outcomes in the management of pelvic pain by the group when compared to the other groups. The chair of obstetrics and gynecology requests that the group complete the process described above and report their results to the chair. If this process identifies uncontrolled variation in the workup and management of pelvic pain, the chair authorizes the group to implement the quality improvement measures that they have identified and report back the results of doing so. Government agencies, such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom, FIGO, and national associations of obstetricians and gynecologists have published evidence-based guidelines that can be used to responsibly minimize variation in the processes of patient care.

### **Ethical Framework**

- 1. The ethical principle of beneficence in professional ethics in obstetrics and gynecology creates the prima facie ethical obligation of the obstetrician-gynecologist to identify and provide clinical management of the patient's condition or diagnosis that, in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment, is predicted to result in net clinical benefit. Such clinical management is known as medically reasonable.
- 2. The ethical principle of healthcare justice in professional ethics in obstetrics and gynecology creates a prima facie ethical obligation of the obstetriciangynecologist to see to it that each patient receives medically reasonable clinical management of her condition or diagnosis.
- 3. Processes of clinical care that display unmanaged variation are not compatible with the beneficence-based and healthcare-justice-based ethical obligations of the obstetrician-gynecologist.
- 4. The informed consent process, which is based on the ethical principles of beneficence and respect for autonomy, is required when the provision of medically reasonable clinical management is reliably judged to entail clinically significant risk. A clinically significant risk is an outcome that clinical management aims to prevent, because it can adversely affect the patient's health, e.g. postoperative infection.
- 5. There is ethical controversy about whether quality improvement is research, i.e. a clinical experiment designed to produce generalizable knowledge.

- 1. Obstetrician-gynecologists and leaders of the specialty have the professional responsibility to improve quality by identifying uncontrolled variation in the processes of patient care and replacing it with responsibly managed variation.
- 2. Obstetrician-gynecologists and leaders of the specialty should advocate for professionally responsible cost control: improving the quality of patient care as the means to responsibly manage costs.

- 3. Obstetrician-gynecologists and leaders of the specialty should advocate against cost control measures that do not include the professional commitment to improve the quality of the processes of patient care.
- 4. When a quality improvement project entails clinically significant risk, there is an ethical obligation to obtain informed consent from patients in advance.
- 5. When a quality improvement project does not entail clinically significant risk, there is no ethical obligation to obtain informed consent from patients.
- 6. Organizational leaders in obstetrics and gynecology should work with their colleagues to create and implement a policy for addressing the controversy about whether and when quality improvement should be considered human subjects research. Such a policy should define when a quality improvement project should be considered research. If a quality improvement project is considered to be research, it should be conducted only with the approval of an Institutional Review Board/Research Ethics Committee.

#### Reference

[1] Bisognano M, Cherouny PH, Gullo S. Applying a science-based method to improve perinatal care: the institute for healthcare improvement perinatal improvement community. *Obstet Gynecol* 2014;124:810-814.

#### Virtual Meeting from New York, New York, USA, July 2020

#### Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 081: Responsibly managing clinical variation to improve quality. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 51–54.

# IV. Clinical Practice of Reproductive Medicine

# **Guideline 016: Sexual and Reproductive Rights**

- 1. Sexual and reproductive rights of individuals are essential components of human rights. These include the rights to:
  - the exercise of motherhood avoiding unnecessary risks of illnesses and death;
  - individual control of fertility;
  - a sexual life free of violence, coercion, or risk of acquiring disease and unwanted pregnancy;
  - termination of pregnancy as legally permitted;
  - the availability of services for the exercise of those rights;
  - information about their rights and the services that ensure them.
- 2. These rights 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 healthcare system, and particularly within the care offered by obstetricians and gynecologists, this statement of human sexual and reproductive rights implies certain ethical imperatives.

#### Recommendations

- 1. Women and men have the right to be educated and decide about a professional 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. Biopsychosocially harmful alteration of female body parts associated with gender or sexual function is unacceptable.

#### London, 2016 revision of 1997 version

#### Citation for 1997 version:

Report of the Committee for the Study of Ethical Aspects of Human Reproduction. Some ethical issues in the doctor/patient relationship. Patenting of human genes. Ethical aspects in the management of newborn infants at the threshold of viability. The ethical aspects of sexual and reproductive rights. Cloning in human reproduction. *Int J Gynecol Obstet* 1997;52(2):165–168. PMID: 9431887.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 016: Sexual and reproductive rights. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 55–56.

# **Guideline 017: Sex Selection for Nonmedical Purposes**

- 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 in the sex composition of populations, to a variable extent.
- 2. The Committee opposes 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 nonmedical reasons vary by country and range from no specific regulation to complete prohibition and criminalization.
- 6. It is possible to select the sex of an embryo or fetus for nonmedical reasons by the same techniques that are usually performed for prevention of sexlinked disorders.
- 7. The techniques for sex selection have expanded throughout preconception and post conception. Preconception sex selection includes sperm separation. Preimplantation 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 villus sampling (CVS), amniocentesis, or sonography are additional means that can identify fetal sex.

#### Recommendations

- 1. The use of sex selection to avoid sex-linked genetic disorders is consistent with professionally responsible clinical practice.
- 2. Because sperm separation and PGD avoid termination of an ongoing pregnancy, they may appear to be less objectionable techniques for sex selection for nonmedical reasons. 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 consistent with professionally responsible clinical practice, which do not contribute to social discrimination on the basis of sex.
- 4. Where a region has a marked sex ratio imbalance, the professional societies should work with governments to ensure that sex selection is strictly regulated to contribute to the elimination of sex discrimination. Regulation can justifiably permit disclosure of sex only for medical reasons.
- 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 and prevent adverse public health and social consequences of sex imbalance in a population.
- 6. Irrespective of the approach to nonmedical sex selection, all health professionals and their societies have the professional responsibility to advocate and promote strategies that will encourage and facilitate the achievement of sex equality.

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on sex selection for non-medical purposes. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2006;92:329–330.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 017: Sex selection for nonmedical purposes. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 57–58.

## Guideline 018: Advocacy for Evidence-Based and Ethically Justified State Regulation of Advances in Reproductive Medicine

#### Background

1. Advances in reproductive medicine occur rapidly and often create unexpected clinical and ethical challenges. There is also variation in the regulation of reproductive medicine from country to country. FIGO therefore proposes a general approach to these challenges, rather than specific responses that risk becoming rapidly outdated. In addition, professional self-regulation does not appear to be an effective tool for the professionally responsible creation and clinical introduction of these advances. The powers of the state to protect public health have traditionally included regulation of biomedical research and clinical practice.

#### Recommendation

 Physicians and their professional associations in each country or federation of countries, such as the European Union, should advocate for evidencebased and ethically justified regulation of advances in research in reproductive medicine and their clinical application. The goals should be to promote professionally responsible innovation and research and thereby protect the health of women, their partners, and future children from untested advances and professionally irresponsible clinical application of such advances.

#### London, July 2018 revision of 2007 version

#### Citation for 2007 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. FIGO Committee Report: Donation of genetic material for human reproduction. *Int J Gynecol Obstet* 2008;102:309-310. doi: 10.1016/j.ijgo.2008.04.015. PMID: 18602633.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 018: Advocacy for evidence-based and ethically justified state regulation of advances in reproductive medicine. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 59.

# Guideline 019: The Sale of Gametes and Embryos

#### Recommendations

- 1. The Committee reaffirmed the former statement made in 1993 that the donation of genetic material should be altruistic and free from commercial exploitation. Reasonable compensation for legitimate expenses is appropriate.
- 2. It should also be noted that when payment is involved, donors may be tempted to withhold personal information which, if known, would make them as donors.

#### London, July 2016 revision of 1997 version

#### Citation for 1997 version:

FIGO Committee for the Study of the Ethical Aspects of Reproductive Medicine and Women's Health. Ethical guidelines on the sale of gametes and embryos. In: *Ethical Issues in Obstetrics and Gynecology*. London: FIGO; 2015:49.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 019: The sale of gametes and embryos. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 60.

# **Guideline 020: Directed Donation of Gametes**

- 1. Directed donation of gametes occurs when the recipients are selected by persons known to them.
- 2. Requests for directed sperm donation are infrequent due to the availability of advanced micromanipulative assisted reproductive technologies. In low-resource 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 the privacy of the donor in contrast to those who choose directed donors.
- 6. The obstetrician-gynecologist has the professional obligation to protect information from directed donation from unauthorized disclosure. The only risk of breach of this obligation will be a legal order to disclose this information.
- 7. The donor and recipient may have different views about their privacy rights. The nature and extent of privacy will therefore be a function of the relationships among the involved parties. There is therefore an inherent risk of loss of privacy.
- 8. 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 many ways, some of them unpredictable.

- 1. The obstetrician-gynecologist has the professional responsibility to lead a thorough informed consent process, with a focus on the psychosocial risks of loss of privacy or legally mandated breach of confidentiality.
- 2. Directed donation has other psychological risks. When it is available, psychological evaluation and counselling should 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.

- 3. The professional responsibility to protect the best interests of the child, a core concept of pediatric ethics, calls for a thorough 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, in situations of disagreement in the family in a way that is not in the child's best interests, or in future medical care of the child. 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.
- 4. 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. They should be made aware that such agreements can be challenged and may not be enforceable.
- 5. 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 of the donors. The obstetrician-gynecologist has the professional responsibility to maintain the confidentiality of the results of the screening. Recipients should be aware that this may result in their not being provided access to such information, regardless of their desire for this information.
- 6. Informed consent to a directed donation should be undertaken without the presence of the recipient. Physicians should attempt to determine whether the voluntariness of the donor's decision making is being adversely affected by undue pressure, coercion, or financial benefits; in such a case, the obstetrician-gynecologist should decline to proceed with the donation.
- 7. Informing children resulting from directed gamete donation of their genetic origins is an important protection against inadvertent consanguinity. The obstetrician-gynecologist should ensure that the donor is not a blood relation of the recipient to a degree that would constitute biological incest.

#### London, July 2017 revision of 2000 version

#### Citation for 2000 version:

FIGO Committee for the Study of the Ethical Aspects of Reproductive Medicine and Women's Health. Donation of genetic material for human reproduction. In: *Ethical Issues in Obstetrics and Gynecology*. London: FIGO; 2015:52-55.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 020: Directed gamete donation. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 60–63.

# Guideline 021: Surrogacy

- 1. Surrogacy describes a reproductive model where a woman carries a pregnancy and delivers a child on behalf of another in which a woman is unable to do so, for instance because of a congenital or acquired uterine abnormality, or because of a serious medical contraindication to pregnancy.
- 2. In all cases, the intention is that the surrogate will relinquish the born child to the commissioning person or people.
- 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 people 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 biological, psychological, and social 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 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 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. Given these concerns, the best interests of the child standard, a core principle of pediatric ethics, puts the burden of proof on the permissibility of surrogate pregnancy.
- 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 economically and socially 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 retains all legal and ethical rights to decision making about all aspects of the clinical management of 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, recognizing that the welfare of the future child is in the equation.

- 11. Openness about the mode of conception in all methods of assisted reproductive technology (ART) has become more common since their inception, with no evidence of detriment, and with the advantage of avoiding the revelation of secrets in moments of stress or distress, and the added possible interest of the child to be aware of his/her genetic background. The added complexity of partial surrogacy compared to full surrogacy, where the commissioning parents are also the genetic parents, means that full surrogacy is the preferable option.
- 12. It is generally accepted where surrogacy is legal, in order to avoid conflicts of interest that might create undue pressure or coercion, that different medical teams should look after the commissioning parents undergoing IVF and the (intended) pregnant surrogate.

- 1. Surrogacy is a method of ART reserved mainly for medical indications. It is controversial when done for social reasons. Even for medical indications, given the concerns about the best interests of future children, all involved parties should be very cautious in their decision-making processes.
- 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 person or people's interest. The commissioning person or people have a strict ethical obligation to respect the decisions of the surrogate mother about the clinical management of her pregnancy. This should be made explicit in the contract.
- 4. Surrogate arrangements should not be commercial and are best arranged by nonprofit-making agencies. Special consideration must be given to transborder reproductive agreements, where there is increased risk of undue inducement of resource-poor women from resource-rich countries' citizens.

- 5. The commissioning person or people 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 applicable law, 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 and its limitations, especially those related to the enforcement of the contract.
- 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.

# London, July 2018 revision of 2007 version

## Citation for 2007 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. FIGO Committee Report: Surrogacy. *Int J Gynecol Obstet* 2008;102:312–313. doi: 10.1016/j.ijgo.2008.04.016. PMID: 18603243.

# Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 021: Surrogacy. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 63–66.

# Guideline 022: Oocyte and Ovarian Cryopreservation

# Background

- 1. 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 offers the potential of a broader range of options in the future.
- 2. 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 in formulating treatment plans for the patient to consider.
- 3. 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 primary means for gestation of a pregnancy resulting from their gametes. This must be taken into account at the time that these techniques are discussed.
- 4. The obstetrician-gynecologist has the professional responsibility to lead a decision-making process that informs the patient about all medically reasonable alternatives for the clinical management of her condition and makes a reasonable effort to ensure that her decision making is voluntary (i.e. free from controlling internal or external influences).
- 5. Hope is the desire for a future state of affairs that has some probability, however small, of occurring. It is not irrational for a patient to strongly desire a future state of affairs that has only a very small probability of occurring, because the patient places a paramount value on that future state of affairs.
- 6. False hope occurs when the patient desires a future state of affairs that is considered to have a probability of zero.

# Recommendations

1. The obstetrician-gynecologist should offer the patient all of the medically reasonable alternatives for the preservation of fertility to patients for whom this is a goal. The most available, standardized, and effective technique

should be offered, such as in vitro fertilization or embryonic freezing, if the reproductive status of the woman makes any of these feasible.

- The obstetrician-gynecologist should inform the patient that cryopreservation of oocytes and ovarian tissue has uncertain efficacy. Access to innovative or research techniques should be limited to centers of excellence that can provide appropriate oversight. The obstetriciangynecologist should inform the patient that innovation and research are not the standard of care.
- 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 in oocyte and ovarian cryopreservation.
- 5. The obstetrician-gynecologist should inform the patient about the costs for freezing and for long-term storage, including information about disposition of cryopreserved gametes or embryos if the storage fee is not paid as agreed.
- 6. When the patient is a legal minor, parents should 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 judgment. 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 child. 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. Obstetrician-gynecologists should be particularly sensitive to the issue of capacity to consent to cryopreservation under applicable law.
- 8. The obstetrician-gynecologist should be attentive to the role of hope in the decision-making process and not label as a false hope what is hope for future fertility when the probability for that outcome is very low. The obstetrician-gynecologist should also be aware of and responsive to premature abandonment of hope by the patient.

9. The obstetrician-gynecologist should be aware of and address factors that could adversely affect the voluntariness of the patient's decision for or against cryopreservation, including false hope.

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical considerations and recommendations on oocyte and ovarian cryopreservation. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2006;92:335–336.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 022: Oocyte and ovarian cryopreservation. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 67–69.

# **Guideline 023: Prenatal Diagnosis and Screening**

- 1. Prenatal screening and diagnosis have become part of the routine antenatal care of pregnant women in resource-rich countries.
- 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 in vitro fertilization (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 noninvasive 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.
- 5. The information obtained by all techniques may lead to reassurance about an ongoing pregnancy, termination of pregnancy, the nontransfer of an affected embryo in an IVF cycle, or to adjustments in future lifestyle. 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 nontransfer of the embryo. Most families do not share this prejudice, but prefer to have a healthy child. Pregnancy termination or nontransfer 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.

- Prior to agreeing to antenatal screening and/or diagnostic procedures, women must be informed and counseled, 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 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 Guideline 017: Sex selection for nonmedical 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, July 2019 revision of 1991 and 2012 versions

## Citation for 2012 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Prenatal diagnosis and screening. *Int J Gynecol Obstet* 2013;120:210–211. doi: 10.1016/j.ijgo.2012.10.004.

# Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 023: Prenatal diagnosis and screening. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 69–71.

# **Guideline 024: Genomics and Proteomics**

# 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.

- 1. Physicians and their professional societies have the professional responsibility to 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. Physicians have the professional responsibility to 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. Physicians have the professional responsibility to ensure that any testing, whether by the internet or on-site, meets carefully explicated requirements and applicable law for counselling as well as for data and tissue protection.
- 4. Physicians have the professional responsibility to ensure that use of biobanks and other tissue and sera repositories is regulated and has research requirements that protect confidentiality and ensure documented informed consent for donation to such banks.

- 5. Physicians have the professional responsibility to 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. Physicians have the professional responsibility to 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. Physicians have the professional responsibility to 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.

## London, July 2018 revision of 2008 version

#### Citation for 2008 version:

Milliez J. Professional obligations related to developments in genomics and proteomics in human testing. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2009;107:79. doi: 10.1016/j.ijgo.2009.03.050. PMID: 19394613.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 024: Genomics and proteomics. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 72–73.

# Guideline 025: latrogenic and Self-Induced Infertility

- latrogenic 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, traditional methods of

treatment of infertility, hydrotubation, and unnecessary pelvic surgery may result in pelvic adhesions causing iatrogenic infertility.

- 3. In high-income countries, iatrogenic infertility is estimated to cause about 5% of male and female infertility. In lower-income countries, it is expected that the incidence of iatrogenic and self-induced infertility would be higher than in high-income countries. This may be due to some traditional practices and 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. latrogenic infertility may occur as a side effect of management of various obstetrical and gynecological conditions such as hysterectomy for postpartum hemorrhage, extensive curettage, radiotherapy and chemotherapy for various malignant diseases during childhood or reproductive age, extensive surgery for benign or malignant diseases of the uterus and the ovary, postoperative adhesions following pelvic surgery, and extensive ovarian drilling for patients with polycystic ovarian syndrome.

- latrogenic infertility may, in some circumstances, be unavoidable and occur as a side effect of necessary surgical or medical procedures to which the patient has consented and about which the patient should have been informed. It is the duty of obstetricians and gynecologists to take all necessary measures to reduce the incidence of iatrogenic infertility, whenever possible. Obstetricians and gynecologists should ensure that women are made aware of this risk in the informed consent process.
- 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, may minimize the incidence of pelvic adhesions.
- 3. Gynecologists and surgeons should also remember that all invasive diagnostic and therapeutic infertility procedures, however simple they may be, 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 B Lynch suture before 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 fertilitysparing 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 autotransplantation 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 traditional methods, unsafe abortion, obstetric fistula, and female genital mutilation will also help to reduce iatrogenic and otherwise-induced infertility.

## London, July 2018 revision of 2006 version

#### Citation for 2006 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on iatrogenic and self-induced infertility. *Int J Gynecol Obstet* 2006; 94:172-173. doi: 10.1016/j.ijgo.2006.06.006.PMID: 16844124.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 025: latrogenic and self-induced infertility. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 73–76.

# **Guideline 026: Cross-Border Reproductive Services**

- 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 healthcare professionals suggest treatment abroad, they have the professional obligation to ensure that, as in any professional referral, they have general knowledge of the safety and quality of care at the site they suggest, for the purpose of facilitating the patient's choices and protecting her health-related interests. 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, cross-border care can overcome limits on patients' autonomy. Healthcare professionals have the professional obligation 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. Physicians should be particularly attentive to women who have obtained information from websites and respectfully correct misinformation, so that women can make informed decisions.

- 5. Potentially harmful outcomes of cross-border reproductive care include medical and legal complications and negative impacts on healthcare 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' healthcare 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 known 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.

- 1. Obstetrician-gynecologists and their national professional societies should support patients' access locally to evidence-based reproductive care in a fair and equitable manner, without discrimination.
- 2. Obstetrician-gynecologists and their national 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 in their country. National professional societies should advocate for effective government oversight to achieve this goal.
- 3. Obstetrician-gynecologists and their 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 patients.

- 4. Provision of counseling that meets accepted professional standards 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 they are receiving clinical management at home that meets accepted professional standards for obtaining and transmitting medical records.
- 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 Guideline 018: Advocacy for Evidence-Based and Ethically Justified State Regulation of Advances in Reproductive Medicine and Guideline 021: Surrogacy.
- 8. Cross-border services including sex selection are unacceptable except in compliance with Guideline 017: Sex selection for nonmedical purposes.
- 9. Cross-border referrals to reproductive care, particularly in low-income countries, should avoid shifting resources in such countries to the care of visiting patients, when doing so results in detrimental compromise of the services available to meet the treatment needs of the resident population.

## London, July 2019 revision of 2012 version

## Citation for 2012 version:

Dickens B. Cross-border reproductive services: FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2010;111:190–191. doi: 10.1016/j.ijgo.2010.07.005. PMID: 20801448.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 026: Cross-border reproductive services. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 76–78.

# **Guideline 027: Fertility Centers and Whom They Should Treat**

# Background

- Based on the best interests of the child standard, a core principle of pediatric ethics, the welfare of a future child must be taken into consideration. This means that a patient's autonomy is balanced with the responsibility towards the future child.
- 2. A patient's autonomy may sometimes clash with the welfare of the future child. 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.

- 1. Decisions about treating or refusing to treat patients should reflect the balance between patients' autonomy and the best interests of the child standard and implications for professional responsibility for the health of 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 centers should treat all requests for assisted reproduction equally without invidious discrimination, such as marital status, sexual orientation, or disability.

- 4. Clinicians should be encouraged to refuse to initiate a treatment option they regard from evidence-based clinical practice as futile, i.e. highly unlikely to result in pregnancy and livebirth, provided that they have informed the patient that they regard the option as futile.
- The 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 ethically controversial to purposely create a child with a disability, and centers may refuse such requests.
- 6. Clinicians may refuse to initiate any treatment option they regard in evidence-based clinical judgment as having a very poor prognosis, i.e. a very small percent chance of pregnancy and livebirth, provided that they fully inform the patients and offer information about referrals, if appropriate.
- 7. Ensuring high success rates in a clinical service or group by not treating patients with poor prognoses should be regarded as ethically impermissible, although age may be used as a cutoff criterion, especially in publicly funded healthcare systems, when a poor success rate makes the treatment almost futile.

## London, July 2018 revision of 2008 version

## Citation for 2008 version:

Milliez J. Fertility centers and who they should treat: FIGO committee for the ethical aspects of human reproduction and women's health. *Int J Gynecol Obstet* 2009;107:166. doi: 10.1016/j.ijgo.2009.07.008. PMID: 19665708.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 027: Fertility centers and whom they should treat. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 79–80.

# Guideline 028: Clinical Applications of Embryonic or Fetal Tissue

# Background

- The use of embryonic or fetal tissue or cell transplants for improving the clinical management of disease and injury 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 necessarily part of the abortion debate, because 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 varies among different countries.
- 2. 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.

- A final decision regarding termination of pregnancy should be made completely separate from and 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.

## London, July 2018 revision of 2007 version

#### Citation for 2007 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. FIGO Committee Report: Guidelines for the use of embryonic or fetal tissue for therapeutic clinical applications. *Int J Gynecol Obstet* 2008;102:311. doi: 10.1016/j.ijgo.2008.04.017. PMID: 18602631.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 028: Clinical applications of embryonic or fetal tissue. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 81–82.

# **V. Clinical Practice of Obstetrics**

# **Guideline 029: Definition of Pregnancy**

Natural human reproduction is a process which involves the production of male and female gametes and their union at fertilization. Pregnancy is that part of the process that commences with the implantation of the fertilized ovum in a woman,[1] and ends with either the birth [2] of a baby 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.

## London, July 2016, unchanged from 1998

#### Citation for 1998 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Gynecol Obstet Invest* 1998;48:73–77.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 029: Definition of pregnancy. In: Chervenak FA, McCullough LB, eds. FIGO *Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 83.

# Guideline 030: Safe Motherhood

- Pregnancy is a condition and not a disease. Pregnancy is a condition that has biopsychosocial benefits and risks. Obstetric care is important for avoiding maternal mortality and morbidity and reducing the unacceptable outcomes of preventable perinatal mortality and morbidity.
- 2. Hemorrhage is the leading cause of maternal death during pregnancy, accounting for more than one-third of all deaths.
- 3. 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 that cannot normally be provided by TBAs.
- 4. 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 obstetric treatment.
- 5. The minimum rate of cesarean delivery to prevent avoidable maternal death is estimated to be around 5%. However, in countries with high maternal mortality, the rate of cesarean delivery is often less than 1% owing to lack of health facilities and trained personnel.
- 6. Contributing factors to maternal mortality are early age at marriage; pregnancy occurring too early (before 18 years of age), too close (with less than 2-year intervals), too late (after 40 years), too frequently; illiteracy; malnutrition; lack of access to proper contraception; and undue trust in the contraceptive value of breastfeeding.
- 7. Half of the pregnancies that occur each year are unplanned. Half of unplanned pregnancies will, in turn, end in induced abortion, about half of which are unsafe abortions. These result in preventable maternal mortality. When countries have introduced legislation to permit abortion for nonmedical reasons, the overall mortality and morbidity from the procedure has fallen dramatically, without any significant increase in the number of induced abortions.

- 1. Women's mortality related to pregnancy remains unacceptably high, particularly in low-income countries and regions. Prevention of maternal death should be considered worldwide as a public health priority. Obstetric professional societies should publicize 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 a main reason for maternal death is an avoidable delay in implementing proper emergency care during complicated labor, 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 healthcare providers who are trained and equipped to provide safe delivery.
- 4. Prenatal and intrapartum care should be organized so that every woman with an obstetric life-threatening complication is transferred without delay to a medical center providing the human and technical resources required for emergency obstetric care, including cesarean delivery and blood transfusion.
- 5. Where abortion is not against the law, every woman should have the right, after appropriate counseling, to have access to medical or surgical abortion. The healthcare 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. See Guideline 048: Postabortion care.
- 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 meeting the financial needs for women, particularly within rural communities and in remote areas.
- 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. See the FIGO Safe Motherhood and Newborn Health Committee guidelines [1].

#### Reference

[1] FIGO Safe Motherhood and Newborn Health Committee. Prevention and treatment of postpartum hemorrhage in low-resource settings. *Int J Gynecol Obstet* 2012;117:108–118.

#### London, July 2019 revision of 2012 version

#### Citation for 2006 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Safe motherhood. *Int J Gynecol Obstet* 2006;94:167–168. doi: 10.1016/j.ijgo.2006.06.004.

#### Citation for 2012 revision of 2006 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Safe motherhood. *Int J Gynecol Obstet* 2013;120:312–313. doi: 10.1016/j.ijgo.2012.10.008.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 030: Safe motherhood. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 84–86.

# **Guideline 031: Adolescent Pregnancies**

- Adolescence is the timeframe during which a combination of physical, psychological, and social changes occurs. According to the WHO, there are 16 million births to adolescent women and many more pregnancies. The WHO also reports an estimate of 4 million unsafe abortions among adolescent women.[1]
- 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. According to the United Nations (UN), pregnancy is the leading cause of death among female adolescents.
- 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 cognitively disabled, those with easy access to substances they abuse, and quite often those whose parents have themselves married during their teenage years.
- 5. 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 selfsufficiency, leading to poverty and an increased risk of repeat pregnancies.
- 7. Adolescent pregnancies cause adverse outcomes, 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 some 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. Lack of awareness of contraceptive options and lack of access to legal and safe abortions may expose pregnant adolescents to the risks of unsafe abortions.

- 1. Healthcare professionals, along with governmental and nongovernmental organizations, should advocate for reproductive and sexual health education both inside and outside schools. This education should be comprehensive and easily accessed 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.
- 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. Parental consent or court approval, however, may be legally required. Healthcare professionals 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 post-abortion 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 healthcare professionals.

#### Reference

[1] World Health Organization. Adolescent Pregnancy. https://www.who.int/news-room/fact-sheets/detail/adolescent-pregnancy. Accessed June 21, 2021.

#### London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Ethical issues in adolescent pregnancies. *Int J Gynecol Obstet* 2015;128:185–186. doi: 10.1016/j.ijgo.2014.10.006. PMID: 25458417.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 031: Adolescent pregnancies. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 86–89.

# **Guideline 032: Multiple Pregnancy**

- 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 20 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 can have obstetric implications for the pregnant woman and her offspring, for the family and the community, and for health service resources particularly where neonatal care services are limited or lacking.

- 5. The obstetrician-gynecologist has the professional responsibility to adhere to evidence-based guidelines, to prevent unplanned multiple pregnancy.
- 6. The obstetrician-gynecologist has the professional responsibility to inform the pregnant woman about the obstetric risks of higher-order multifetal pregnancy and that these risks can be reduced by selective termination.

- 1. In order to prevent iatrogenic risks of multiple pregnancy, every obstetriciangynecologist must adhere to evidence-based guidelines for embryo transfer and administration of superovulatory medications.
- 2. In order to prevent iatrogenic risks of multiple pregnancy, the obstetriciangynecologist should strongly recommend against self-treatment with superovulatory drugs.
- 3. The obstetrician-gynecologist should inform women with a multiple pregnancy, especially higher-order pregnancies, about the risks of such pregnancies, especially extreme prematurity and its complications.
- 4. Early in pregnancy, the obstetrician-gynecologist should inform women with a high-order multiple pregnancy about how these risks can be reduced, including adhering to the plan for prenatal care and selective termination.
- 5. Obstetrician-gynecologists have the professional responsibility to make the public 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 areas.
- 6. People seeking treatment for infertility should be informed about the risk of a multifetal pregnancy, including the risk that they may confront an unwelcome decision about selective termination.
- 7. When discussing their results in public, obstetrician-gynecologists should never describe triplet or higher-order multiple pregnancies as a success but always as a complication of treatment. The media should be aware that best professional opinion is to regard higher-order multiple pregnancies as a complication.

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical recommendations on multiple pregnancy and multifetal reduction. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2006;92:331–332.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 032: Multiple pregnancy. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 89–91.

# **Guideline 033: Intrapartum 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 a way that provides a healthy environment and are usually ready to take reasonable risks on behalf of their fetus and future child, there may be situations where their interests do not coincide. The pregnant woman's behavior may create risks for herself and her fetus (e.g. use of drugs, tobacco, and alcohol; not attending appropriately provided prenatal care; failure to take available HIV therapy). The pregnant woman may choose not to accept diagnostic, medical, or surgical procedures aimed at preserving fetal well-being, including cesarean delivery for fetal indications.

- The obstetrician has the professional responsibility to support informed decision making by the pregnant woman. The decision-making process should be initiated before the intrapartum period, with the goal of eliciting the pregnant woman's views about indicated cesarean delivery, so that any concerns and questions she may have can be addressed well in advance. This is known as the preventive ethics approach to intrapartum decision making. The obstetrician should counsel the pregnant woman with empathy and patience and provide such support services as are needed to achieve the best maternal and fetal outcomes. Refusal of cesarean delivery should be addressed using respectful persuasion, to prevent conflict during the intrapartum period. See Guideline 008: Patients' refusal of recommended treatment.
- 2. There are extremely rare clinical circumstances, such as well-documented, intrapartum, complete placenta previa, for which cesarean delivery is the only safe form of clinical management for the pregnant, fetal, and neonatal patient. If respectful persuasion fails to achieve the pregnant patient's informed consent to cesarean delivery, it is ethically permissible to perform cesarean delivery, as the least worst option, when expressly permitted in organizational policy and applicable law and when the pregnant patient does not physically resist.
- 3. When a pregnant patient's decision-making capacity is irreversibly impaired, surrogate decision making is required. The surrogate decision maker should first attempt to satisfy the substituted judgment standard by basing decision making on the patient's reliably identified values and beliefs. When the surrogate decision maker is not able to meet this standard, the best interests of the patient standard applies and should take into account the clinical interests of the pregnant, fetal, and neonatal patient. Information from the family and others may help to ascertain what she would have wanted.
- 4. In some legal jurisdictions, pregnant minors can make their own decisions about obstetric management. In jurisdictions in which this is not the case, the decisions of pregnant minors who have the capacity to participate in decision making should be respected and therefore have their decisions taken into account by the surrogate decision maker, usually the pregnant patient's parent(s) or guardian.

#### London, July 2019 revision of 2011 version

#### Citation for 2011 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health; International Federation of Gynecology and Obstetrics. Ethical guidelines regarding interventions for fetal wellbeing. *Int J Gynecol Obstet* 2011;115:92. doi: 10.1016/ j.ijgo.2011.07.006.

#### Citation for 2020 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 033: Intrapartum interventions for fetal well-being. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 91–93.

# **Guideline 034: Pregnancy and HIV-Positive Patients**

#### Background

#### Public health considerations

- 1. Women make up more than half of the people living with HIV worldwide, particularly in sub-Saharan Africa.
- 2. In the majority of cases, HIV infection has been heterosexually acquired with infection diagnosed during pregnancy.
- 3. HIV infection is a public health challenge that requires effective prevention and treatment.
- 4. Effective responses by governments and nongovernmental organizations (NGOs) require reliable data about incidence and prevalence.
- 5. Effective responses also require change in behavior that is known to cause transmission to sexual partners, needle sharers, and infants.

#### **Clinical considerations**

- 1. HIV infection should be considered a chronic disease that is manageable if patients have access to effective therapy such as combination antiretroviral therapy (cART). In this respect, HIV infection is not clinically unique.
- 2. For pregnant women with access to effective treatment, vertical transmission can be greatly reduced.

# Social considerations

- 1. Women with HIV infection are at risk for marginalization in many societies.
- 2. In many societies, women are in subordinate relations, which can impede prevention, treatment, and collection of data needed to estimate incidence and prevalence.
- 3. In many societies, disclosure of HIV seropositivity to those without authorized access to this information can result in discrimination, reluctance of women to seek health care, and negative perceptions of the origins of infection.
- 4. Nonauthorized disclosure of HIV seropositivity can also impede collection of data needed to estimate incidence and prevalence.

# **Ethical framework**

A professionally responsible approach to women with HIV infection or at risk for HIV infection requires physicians to identify and balance the requirements of public health ethics, clinical ethics, and human-rights ethics.

# **Public health ethics**

- 1. Public health ethics emphasizes the ethical principle of beneficence, which requires effective prevention and treatment of communicable diseases, to reduce the burden of disease on individuals, communities, societies, and public and private payers for health care.
- 2. In public health ethics, individuals who are vectors of communicable disease have a beneficence-based obligation to others to prevent exposure, especially when those others cannot consent to the exposure.
- 3. These beneficence-based obligations justifiably limit patient autonomy, a major difference between public health ethics and clinical ethics.

# **Clinical ethics**

- 1. As a matter of professional responsibility, obstetrician-gynecologists have the ethical obligation to ensure that every patient receives clinical management of her condition that is supported by deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment.
- As a matter of professional responsibility, obstetrician-gynecologists have the ethical obligation to support the health of the entire population of patients. Obstetrician-gynecologists have the ethical obligation to advocate for HIV-

infected women and children, as well as women and children at risk for HIV infection.

#### Human-rights ethics

- 1. Discrimination against individuals on grounds of HIV seropositivity violates their human rights. As a matter of professional responsibility, physicians should therefore not participate, deliberately or by oversight, in this form of discrimination or allow it by their staff members.
- 2. All patients have the human right to effective clinical management of their health conditions, including prevention and treatment of communicable diseases.

- 1. HIV-positive patients must not be subjected to denial of clinical care, or inferior clinical care, on account of their HIV status.
- 2. Obstetrician-gynecologists and their staff have the professional responsibility to be familiar with the most recent guidelines for the care of HIV-infected women who are pregnant or want to become pregnant and for the case of infected infants, relevant to the resources actually and potentially available for patient care.
- 3. Obstetrician-gynecologists and their staffs must observe strict confidentiality of the HIV status of all patients, according to ethical standards and applicable law about authorized access to such protected health information.
- 4. There are three approaches to testing for HIV seropositivity.
  - a. "Opt-out" testing (all patients are tested for HIV status unless they refuse) is the preferred approach. From the perspective of public health ethics, this is an effective way to gather data on incidence and prevalence and to support HIV-infected patients from becoming vectors for infection of others. From the perspective of public health ethics, the resulting limitations on patient autonomy are justified. From the perspective of human rights and clinical ethics, the patient's right to refuse testing is preserved.
  - b. From the public health perspective, "opt-in" testing (only patients who consent are tested) is an unreliable way to gather data on incidence and prevalence and to support HIV-infected patients from becoming vectors for infection of others. From the perspective of human rights and clinical

ethics, the patient's right to refuse testing is preserved. On balance, the "opt-in" approach is not preferred.

- c. Mandatory testing should be considered only after "opt-out" testing has been shown to fail to accomplish its public health goals and faces a very steep burden of proof. Careful consideration should be given to whether mandatory testing might only reinforce the failure to achieve public health goals. In addition, mandatory testing violates human rights and patient autonomy.
- 5. HIV-positive women should not be discouraged from becoming pregnant. They should be properly counseled about their HIV status and its clinical management. They should be informed about the need to cooperate with guidelines-based clinical management of pregnancy and adherence to cART regimen for maternal health and minimization of vertical transmission.
- 6. From the perspectives of clinical ethics and human-rights ethics there is a professional responsibility to protect the right of all pregnant women, including those with HIV infection, to make decisions with their obstetriciangynecologist about the disposition and management of pregnancy. HIV seropositivity should not become the grounds for whether induced abortion is allowed or denied. No woman should ever be forced to have an induced abortion or to be sterilized on the basis of her HIV status. From the perspective of public health ethics, these extreme measures will risk undermining the public trust that is essential for the success of an effective public-health response to HIV infection.
- 7. From the perspectives of clinical ethics and human-rights ethics there is a professional responsibility not to make decisions about limiting access to or continued provision of life-sustaining treatment based solely on HIV status.

#### London, July 2017 revision of 2008 and 2012 versions

#### Citation for 2008 version:

Milliez J. Pregnancy and HIV-positive patients. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2009;107:77–78. doi: 10.1016/j.ijgo.2009.03.046.

#### Citation for 2012 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Ethical aspects of HIV infection and reproduction. *Int J Gynecol Obstet* 2013;120:309. doi: 10.1016/j.ijgo.2012.10.006.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 034: Pregnancy and HIV-positive patients In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology.* London: FIGO; 2021: 93–97.

# **Guideline 035: HIV and Fertility Treatment**

- 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 but clinically manageable 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 high-income 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 and individuals should currently be restricted to specialized centers. 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 low-income and middleincome countries that struggle to afford the benefits of ARV treatment is of grave ethical concern. In these countries this challenge may be compounded by the unavailability of basic medical services in some areas. 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 infection-control 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 behavior and life-style issues, and social support network if the infected individual becomes seriously ill or dies.

- 6. Education about viral transmission and prevention is essential, including the education of healthcare professionals and laboratory personnel. Education about known preventive measures such as protected intercourse at all times, intrauterine insemination with washed sperm, or other techniques if warranted by relative infertility, is important.
- 7. Facilities should establish and follow organization policy for infection control, taking into account the need to prevent identification and stigmatization of HIV-infected patients.

- 1. Obstetrician-gynecologists should educate their patients about testing for HIV and other sexually transmitted infections.
- 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 ethically justified 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, should be promoted on an equitable basis.
- 4. Access to assisted reproduction should be free from discrimination.
- 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 organizations of FIGO and individual practitioners.
- 6. Prevention, including education about high-risk behavior, is essential. The need for responsible behavior to avoid spreading the virus and prevent its transmission to the future child, including the necessity to accept ARV treatment during pregnancy, should be emphasized.
- 7. Healthcare providers should ensure that they, their colleagues, and laboratory personnel have the training and resources to implement effective infection-control policies. Seropositive healthcare providers have an ethical

obligation to ensure that they engage in no behavior that puts patients at preventable risk.

#### London, July 2019 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. HIV and fertility treatment. *Int J Gynecol Obstet* 2006;93:187–188. doi: 10.1016/j.ijgo.2006.03.009.

#### Citation for 2020 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 035: HIV and fertility treatment. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 97–99.

# Guideline 036: Decision Making about Vaginal and Cesarean Delivery

#### Background

1. Professionally responsible decision making with patients is based primarily on the ethical principles of beneficence and respect for autonomy. The physician has the beneficence-based obligation to identify and present the medically reasonable alternatives for the clinical management of the patient's condition. In obstetrics "medically reasonable" means that a form of clinical management is technically feasible and in evidence-based clinical judgment is reliably expected to result in net clinical benefit for the pregnant woman, fetus, and neonate. In presenting the medically reasonable alternatives there are distinct roles for directive counseling (defined as making evidencebased recommendations) and nondirective counseling (defined as presenting but not recommending medically reasonable alternatives). Both forms of counseling implement the ethical principle of respect for autonomy by empowering the pregnant woman with the clinical information that she needs to make an informed decision.

- 2. Counseling should be directive when it is certain there is only one medically reasonable option. Counseling should be nondirective when the clinical indications for cesarean delivery are uncertain.
- In most cases there are no evidence-based clinical indications for cesarean delivery. This means that a clinical judgment in favor of cesarean delivery as a medically reasonable alternative bears the burden of proof.
- 4. A patient's request for a form of clinical management does not, by itself, establish that the request is medically reasonable. The clinical judgment of medical reasonableness of a form of clinical management requires a level of clinical expertise that very few patients have. The goal in responding to a patient's request should be to transform it into an informed decision about the medically reasonable alternatives.
- 5. The individual or group self-interests of physicians in such matters as payment or convenience, because they can bias both the physician's clinical judgment and the woman's decision making, have no place in counseling the pregnant woman (see Guideline 011: Responsibly managing conflicts of interest in clinical practice and research).

- 1. Recommending vaginal delivery
- When there are no evidence-based clinical indications for cesarean delivery, vaginal delivery should be recommended. The clinical significance of the absence of an evidence base for cesarean delivery should be explained to the pregnant woman. The obstetrician-gynecologist should explain that, when there is no evidence base supporting cesarean delivery, vaginal delivery is safer than cesarean delivery for both mother and baby.
- Recommending cesarean delivery
   Cesarean delivery should be recommended as the only medically reasonable
   alternative if and only if there is certainty of an evidence base for the clinical
   judgment that cesarean delivery is clinically superior to vaginal delivery.
- Offering both vaginal and cesarean delivery Vaginal delivery and cesarean delivery should both be offered as medically reasonable alternatives when there exists clinical uncertainty about the relative clinical benefits and risks of each.
- Management of self-interest
   It is impermissible in the professional ethics of obstetrics and gynecology to wittingly bias decision making on the basis of individual or group self-interest
in compensation, convenience, or any other form of self-interest. To prevent this bias, the obstetrician-gynecologist should prospectively identify and constantly remain aware of such self-interests and never include them as a basis for clinical judgment about the medical reasonableness of vaginal or cesarean delivery. The way to accomplish this goal is to adhere strictly to the intellectual discipline of evidence-based clinical reasoning.

- 5. Responding to patient's requests Sometimes a patient may request a mode of delivery that the obstetriciangynecologist does not recommend. The obstetrician-gynecologist should never take personally a patient's request for a mode of delivery that lacks an evidence base, because this response can bias subsequent counseling. The obstetrician-gynecologist should ask the patient for her reasons and listen for incomplete or mistaken beliefs, and respectfully correct them. The obstetrician-gynecologist should then explain the evidence base for the recommendation that was made and repeat the recommendation. The patient should be asked to reconsider, especially if her stated reasons support the obstetrician-gynecologist's recommendation. If, after these efforts to inform the patient's request have been completed and she is therefore able to make an informed and voluntary request, it is ethically permissible to implement her request.
- 6. Preventive ethics

The obstetrician-gynecologist should take advantage of prenatal visits to initiate decision making with the pregnant woman about the clinical management of her pregnancy, including intrapartum management. This is known as a preventive ethics approach to decision making with pregnant patients. The clinical reality that a low-risk pregnancy can suddenly and without warning become a high-risk pregnancy should be explained along with the potential of this change to make cesarean delivery something that must be considered for either maternal or fetal indications. The goal should be a mutually acceptable birth plan to manage such an eventuality or other concerns that the pregnant woman may have.

## London, July 2018 (new)

## Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 036: Decision making about vaginal and cesarean delivery. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 99–102.

# **Guideline 037: Cesarean Delivery for Nonmedical Reasons**

## Background

- The medical profession throughout the world has been concerned for many years about the increasing rate of cesarean delivery. Many factors, medical, legal, psychological, social, and financial (including for example higher payments to physicians for cesarean delivery), have contributed to this increase. Efforts to reduce the excessive use of this procedure have been disappointing.
- 2. Cesarean delivery is a surgical intervention with potential hazards for both mother and child. It also uses more healthcare resources than vaginal delivery.
- 3. Physicians have a professional duty to do nothing that may result in net clinical harm to their patients. They also have an ethical duty to society to allocate healthcare resources wisely to procedures and treatments for which there is clear evidence of a net clinical benefit. Physicians are not obligated to perform an intervention for which there is insufficient evidence of net clinical benefit.
- 4. Recently in some societies obstetricians have had increasing requests from women for cesarean delivery for non-indicated reasons.

## Recommendations

1. There is no professional obligation to routinely offer nonmedically indicated cesarean delivery. In response to a woman's request for nonmedically indicated cesarean delivery, obstetricians should recommend against it and recommend vaginal delivery. For a well-informed woman who has

been appropriately counseled by her physician, performing a nonmedically indicated cesarean delivery is ethically appropriate.

2. Physicians have the professional responsibility to inform and counsel women. There is a professional responsibility to prevent the influence of potentially coercive factors such as psychological pressure, social expectations, or the physician's self interest in payment or convenience.

## London, July 2016 revision of 1996 version

### Citation for 1996 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Gynecol Obstet Invest* 1998;48:73–77.

## Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 037: Cesarean delivery for nonmedical reasons. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 102–103.

# **Guideline 038: Planned Home Birth**

- In all regions, access to planned hospital birth can vary for geographic, socioeconomic, and cultural reasons as well as hospital capability. The training and qualifications of attendants at planned home birth and transfer time to a clinic or hospital may vary. These and other factors can increase the perinatal and maternal mortality and morbidity of childbirth. The humanization of childbirth is an important goal in all settings.
- 2. FIGO reaffirms its long-standing commitment to collaborative obstetricianmidwife-attended planned hospital birth.
- 3. Like all forms of clinical management, childbirth should be assessed in professional clinical judgment on the basis of evidence for its safety and patient satisfaction. Perinatal, neonatal, and maternal outcomes of mortality and morbidity should be identified from scientifically and clinically reliable sources and assessed for safety and patient satisfaction, using accepted

scientific methods. Outcomes data should be used to improve the safety of childbirth and patient satisfaction.

- In some regions, there are integrated childbirth systems that may result in similar outcomes between planned hospital birth and planned home birth. In these regions planned home birth and planned hospital birth can both be considered medically reasonable.
- 5. In other regions, especially those without integrated childbirth systems and effective transfer to the hospital and without consistent training and certification of midwives, the mortality and morbidity of planned home birth may be worse. This should be considered clinically unacceptable, because the increased mortality and morbidity of planned home birth can be prevented by planned hospital birth. When this is the case, planned home birth should be considered an unsafe form of childbirth and therefore not a medically reasonable alternative.

- 1. In regions in which planned home birth and planned hospital birth have clinically similar outcomes, and with the consent of the pregnant patient, offering and attending a planned home birth are consistent with professional responsibility.
- 2. In regions in which planned home birth and planned hospital birth have clinically similar outcomes, obstetrician-gynecologists and their national societies should advocate for resources required to improve the safety and patient satisfaction of both planned home birth and planned hospital birth.
- 3. In regions in which planned home birth and planned hospital birth have clinically dissimilar outcomes, offering and attending a planned home birth are inconsistent with professional responsibility.
- 4. In regions in which planned home birth is not consistent with professional responsibility, the obstetrician-gynecologist should explain the evidence-based clinical judgment that planned home birth is an unsafe setting for childbirth, recommend against planned home birth, and recommend planned hospital birth.
- 5. In regions in which planned home birth is not consistent with professional responsibility, obstetrician-gynecologists and their national societies should advocate for public health policies that discourage planned home birth and that direct resources toward the continuous improvement of access to and the safety and patient satisfaction of planned hospital birth.

- 6. In geographically isolated or hard-to-reach regions in which planned home birth by necessity remains the primary form of childbirth, obstetriciangynecologists and their national societies should advocate for improving the outcomes of childbirth, for example, increased training of midwives and prepartum transfer to a hospital.
- 7. Obstetrician-gynecologists should take an evidence-based approach to decreasing the rate of cesarean delivery and of other intrapartum interventions, when in evidence-based clinical judgment such interventions do not improve outcomes. This is an important component of the humanization of childbirth in the hospital setting.
- 8. To improve patient satisfaction, obstetrician-gynecologists should advocate for the organizational resources required to create a home-like setting in the hospital consistent with the professional commitment to patient safety. This is another important component of the humanization of childbirth in the hospital setting.

### London, July 2019 revision of 2012 version

#### Citation for 2012 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Planned home birth. *Int J Gynecol Obstet* 2013;120:204–205. doi: 10.1016/j.ijgo.2012.10.001. PMID: 23199803.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 038: Planned home birth. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 103–105.

## Guideline 039: Brain Death and Continued 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, as determined using accepted criteria.

- 2. Brain death implies irreversible 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 disability.
- 3. The outcomes of continued pregnancy in a cadaver are very mixed and do not support a reliable prediction of survival and live birth. This means that continued pregnancy in a cadaver is an experiment. There is no professional obligation to conduct an experiment in any patient or cadaver.

## Recommendations

 The professionally responsible approach to continuing a pregnancy in a cadaver is to submit a protocol either for innovation (an experiment undertaken to benefit a single fetal patient) or for research (an experiment on a group of fetal patients to investigate whether outcomes can be improved) to the appropriate organizational review process. If this innovation or research is approved, it should only be offered as innovation or research and not as accepted treatment.

## London, July 2019 revision of 2012 version

## Citation for 2012 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Brain death and pregnancy. *Int J Gynecol Obstet* 2011;115:84–85. doi: 10.1016/ j.ijgo.2011.07.002. PMID: 21839449.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 039: Brain death and continued pregnancy. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 105–106.

# **Guideline 040: Anencephaly and Organ Transplantation**

## Background

- Professional responsibility for patients prohibits removal of organs for transplantation from a neonatal patient until the patient has been determined to be dead, either by cardiopulmonary criteria or by brain function criteria. This is called the dead donor rule.
- 2. An infant with an encephaly who shows signs of life is alive. The dead donor rule does not apply. An an encephalic infant who is stillborn does meet the dead donor rule.

## Recommendations

- 1. It is impermissible in the ethics of obstetrics and gynecology, as well as pediatrics, to remove organs from a living anencephalic infant for transplantation into other patients.
- 2. It is permissible in the ethics of obstetrics and gynecology, as well as pediatrics, to remove organs from a dead anencephalic infant for transplantation into other patients.
- 3. It is ethically permissible to continue or initiate perfusion for the purpose of procuring organs after death has occurred, provided that these organs are candidates for procurement and transplantation.
- 4. The ethical permissibility and impermissibility of procuring organs from anencephalic infants should be explained to the pregnant woman, so that her decisions about the clinical management of her pregnancy are informed.

## London, July 2018 revision of 2007 version

## Citation for 2007 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Anencephaly and organ transplantation. *Int J Gynecol Obstet* 2008;102:99. doi: 10.1016/j.ijgo.2008.03.001. PMID: 18423469.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 040: Anencephaly and organ transplantation. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 107.

# Guideline 041: Obstetric Fistula

- 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 low-income countries is obstetric fistula. Obstetric fistula is a preventable complication of labor that occurs when a woman endures prolonged obstructed labor 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 high-income countries through improved obstetric care. However, today millions of women are living with obstetric fistula in lower-income 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 lower-income countries where maternal mortality is high, fistula may occur at a rate of two to three cases per 1000 pregnancies.
- 3. Several sociocultural and health system factors contribute to the prevalence of obstetric fistula in lower-income countries. These include lack of emergency obstetric care, young age at first pregnancy and labor, practice of severe forms of female genital mutilation, gender discrimination, poverty, malnutrition, and poor health service.
- 4. The biological, psychological, and social 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 may be unaware that treatment is available and some treatment may not be affordable.
- 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%. After successful treatment, most women can resume full activities, although subsequent delivery should be by cesarean section.

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

- 1. Priority should be given to ensure access to adequate health care for all women during pregnancy and labor, and to provide emergency obstetric care for those women who develop complications during delivery.
- 2. The reduction of obstetric fistula requires the improvement of the social determinants of health, empowerment of women, the discouragement of early marriage, early childbirth, and high parity, and requires making family planning widely available.
- 3. Appropriate strategies are needed for the eradication of female genital mutilation, which can be a cause of obstructed labor in many low-resource countries.
- 4. Until we succeed in eliminating obstetric fistula, priority should be given to building capacity for fistula repair by establishing specialized training and adequately equipped centers. All countries have a major role to play in fulfilling this goal.
- 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 specialized regional hospitals.
- 6. Prevention and treatment of obstetric fistula should be properly covered in the curriculum of reproductive health in the medical schools in low-resource 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 prevention should be prepared and tailored to suit different audiences in the target communities. Healthcare providers should make alliances among civil society, community, and religious leaders to address the hidden and severe tragedy of obstetric fistula.
- 8. Obstetrician-gynecologists and their national societies should advocate with their governments to develop national strategies to eliminate and treat 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, July 2018 revision of 2006 version

#### Citation for 2006 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on obstetric fistula. *Int J Gynecol Obstet* 2006;94:174–175. doi: 10.1016/j.ijgo.2006.06.007. PMID: 16844123

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 041: Obstetric fistula. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 108–110.

# Guideline 080: Ethical Challenges of the COVID-19 Pandemic

- The COVID-19 pandemic has affected almost every country in the world, some more than others, and with unpredictable severity levels. The response to the pandemic in countries and regions has varied, with varying levels of success in containment. The most successful responses appear to have occurred in countries with equitable healthcare systems, an important macro-level consideration.
- FIGO has provided its members resources on the scientific and clinical challenges of the pandemic for obstetrician-gynecologists and their patients [1].
- 3. The World Health Organization has provided general guidance [2].
- 4. National associations of obstetricians and gynecologists have also provided guidance to their members.
- 5. Pandemics create ethical challenges for physicians in all specialties and especially for obstetrics and gynecology. Fear and stress in the early stages of the COVID-19 pandemic mirrored other pandemics, in that scientific and clinical information was limited and treatment and prevention were in

their infancy, factors that were exacerbated by the shortage of personal protective equipment.

- 6. Professionally responsible care of a pregnant patient with COVID-19 disease requires a multidisciplinary team, with sustained coordination with infectious disease and epidemiology.
- 7. There is no evidence that a spouse or other companion assisting in vaginal delivery who follows accepted infection control measures creates an unacceptable risk of horizontal transmission to the patient or healthcare team.

## **Ethical framework**

- 1. An essential component of professional ethics in obstetrics and gynecology is the life-long commitment to scientific and clinical competence, as a matter of professional integrity.
- 2. The ethical principle of beneficence in professional ethics in obstetrics and gynecology creates the prima facie ethical obligation of the obstetrician-gynecologist to identify and provide clinical management of the patient's condition or diagnosis that, in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment, is predicted to result in net clinical benefit. Such clinical management is known as medically reasonable.
- 3. The ethical principle of respect for autonomy obligates the physician to empower the patient to make informed decisions about clinical management of her condition by providing her with an unbiased presentation of information about the medically reasonable alternatives for the management of her condition and the clinical benefits and risks of each medically reasonable alternative and to support her decision making.
- 4. The ethical principle of healthcare justice in professional ethics in obstetrics and gynecology creates a prima facie ethical obligation of the obstetriciangynecologist to make sure that each patient receives medically reasonable clinical management of her condition or diagnosis.
- 5. The professional virtue of self-sacrifice requires the physician to accept reasonable limits on the physician's self-interest in order to fulfill the commitment to putting the patient's interests first, and to accept limits on group self-interest to fulfill the commitment to maintain the profession of medicine as a public trust.
- 6. All women and men have the fundamental human sexual and reproductive 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 on Economic, Social and Cultural Rights (1975); the International Convention on the Elimination of All Forms of Discrimination against Women (1979); and the 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), the UNESCO Declaration on Bioethics and Human Rights (article 6) 2005, and the World Health Organization (WHO) (2017). Many countries have enumerated human rights and provided for their protection and implementation in law.

- 7. Every patient has a legitimate self-interest in participating in infection control measures, to protect her own health and life. Patients also have a beneficence-based ethical obligation to prevent harm to their obstetricians and other healthcare professionals by participating in infection control measures, to protect the health and life of team members. This is simply a clinical application of what is known in general ethical theory as the harm principle.
- 8. The spouse or other companion supporting the patient in a vaginal delivery has a beneficence-based ethical obligation to prevent risk of horizontal transmission to the pregnant patient, neonatal patient, other patients, and the healthcare team. This is simply a clinical application of what is known in general ethical theory as the harm principle.
- 9. Obstetricians and all other specialists have both beneficence-based and healthcare-justice-based ethical obligations to protect the life and health of all of the patients served by a healthcare organization. Fulfilling these ethical obligations may require "frame-shifting" away from meeting the needs of obstetric patients to meeting the needs of the entire population of patients of a healthcare organization in the allocation of its resources.

## Recommendations

 Obstetricians and gynecologists have the integrity-based ethical obligation to remain updated on the rapidly evolving information about the COVID-19 pandemic and its implications for obstetric and gynecologic practice. This ethical obligation can be readily fulfilled by periodically consulting resources on COVID-19 and pregnancy such as FIGO, WHO, and national associations of obstetricians and gynecologists.

- 2. FIGO member societies should advocate against proposed restrictions on human sexual and reproductive rights in public policy responses by governments to the COVID-19 pandemic.
- 3. An organizational policy of limiting elective procedures may be justified by healthcare justice as a measure to conserve resources for all patients gravely ill in a hospital with COVID-19 disease. However, inasmuch as termination of pregnancy is time-sensitive, it should not be classified as "elective" but as an essential component of patient care.
- 4. Healthcare organizations have a healthcare-justice-based ethical obligation to make sure that the human and material resources necessary to provide equitable healthcare resources for obstetric services are available, to ensure that laboring women have access to medically reasonable clinical management, including rapid access to indicated cesarean delivery. These resources should be protected from diversion to other services. This is known as "ring-fencing" of obstetric services. As necessary to protect pregnant patients, obstetrician-gynecologists should advocate for evidencebased ring-fencing of obstetric resources. Obstetrician-gynecologists should join with other specialists to engage in unified advocacy for ring-fencing all medically reasonable clinical management for essential clinical care, including treatment of cancer and other conditions and diagnoses for which postponement of treatment is not medically reasonable.
- 5. Obstetrician-gynecologists have the beneficence-based ethical obligation to be aware of and seek to prevent psychosocial aspects of containment measures, e.g. the risk that a shelter-in-place policy may increase the risk of spousal economic, psychological, or physical abuse.
- 6. Obstetrician-gynecologists have the beneficence-based ethical obligation to be aware of and seek to prevent mental health aspects of containment measures, e.g. increased risk of onset or exacerbation of anxiety, depression, and other mental disorders, particularly among geriatric female patients who live alone.
- 7. The fulfillment of the ethical obligation to take reasonable risks to one's health and life, which originates in the professional virtue of selfsacrifice, creates the correlative right against healthcare organizations and governments of obstetrician-gynecologists to be provided effective infection control materials, including personal protective equipment. Member societies should advocate for the resources required to implement this right routinely in clinical practice and education.

- 8. Since at least the middle of the 19th century the ethical obligation not to flee during times of contagion has been recognized, along with the prerogative of physicians to relocate their families to safety. The use of accepted infection control measures reduces personal risk of obstetricians to a minimum, making such risk acceptable from the perspective of the professional virtue of self-sacrifice. Obstetricians should fulfill their ethical obligation to continue to provide obstetric care to their patients, provided that effective infection control measures are feasible. Obstetricians should be compensated for provision of patient care; provision of care to patients with COVID-19 is no exception.
- 9. Obstetric educators should advocate for the continued clinical instruction of learners when their involvement does not create unreasonable risk to patients and when their use of personal protective equipment does not result in shortages for healthcare team members. When either of these conditions cannot be met, obstetric educators should advocate for nonclinical teaching of learners, to minimize disruption to their progress toward degrees and certification.
- 10. In extreme circumstances, the needs of a population of patients may threaten to overwhelm an organization's resources. When this occurs, obstetricians have beneficence-based and healthcare-justice-based ethical obligations to accept the need for frameshifting in decision making about the allocation of organizational resources to meet the needs of the entire population of patients served by a healthcare organization. At the same time, obstetricians should advocate for the recognition of limits on such resource allocation created by ethically justified ring-fencing of obstetric resources.

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[1] FIGO website. FIGO COVID-19 Resources. https://www.figo.org/resources/covid-19-resources. Accessed 14 May 2021.

[2] WHO website. Coronavirus disease (COVID-19) pandemic. https://www.who.int/ emergencies/diseases/novel-coronavirus-2019?gclid=EAIaIQobChMIgJz6xuvy6QIVTfDACh 12RAC9EAAYASAAEgIr3vD\_BwE. Accessed 14 May 2021.

## Virtual Meeting from New York, New York, USA, July 2020

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FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 080: Ethical Challenges of the COVID-19 pandemic. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 110–115.

# **VI. Clinical Practice of Gynecology**

# Guideline 042: Counselling Women about Contraceptive Methods

## Background

- 1. The ethical 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.
- 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.

- 1. Respect for informed choice requires that information on contraceptive methods should be provided without coercion to every woman considering using them, including:
  - proper use;
  - contraindications;

- effectiveness in preventing pregnancy;
- continuing to protect against sexually transmitted infections;
- possible side-effects;
- possible interaction with other drugs or conditions.
- 2. Respect for women's autonomy requires that each woman should be explicitly informed that at any time she can decide to stop using the reversible method she chooses.
- 3. Healthcare professionals are ethically required to work to eliminate obstacles to informed choice. To that end, among other efforts, power imbalances must be acknowledged and minimized. 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.
- 4. The professional 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.

## London, July 2016 revision of 1997 version

## Citation for 1997 version:

Schenker JG. FIGO News. Report of the FIGO Committee for the Study of Ethical Aspects of Human Reproduction. International Federation of Gynecology and Obstetrics. *Int J Gynecol Obstet* 1997;57:333–337. doi: 10.1016/s0020-7292(97)02855-5.

## Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 042: Counseling women about contraceptive methods. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 116–117.

# **Guideline 043: Emergency Contraception**

## Background

- 1. In unprotected intercourse, emergency contraception is highly effective in diminishing the number of unwanted pregnancies without the need for an abortion. Evidence suggests that abortion rates among teenagers drop following access to information and use of emergency contraception.
- 2. There is a human right to health, which includes the freedom to control sexual and reproductive health. Implementing this right requires implementing the right to enjoy the benefits of new scientific knowledge in sexual and reproductive health.
- 3. The obstetrician-gynecologist has the professional responsibility to offer emergency contraception, except in cases of known or suspected pregnancy, for the management of unprotected sexual intercourse. It is not ethically permissible to exclude this disclosure on the grounds of the obstetriciangynecologist's beliefs about the moral acceptability of emergency contraception.

- 1. The obstetrician-gynecologist should offer emergency contraception for the management of unprotected sexual intercourse.
- 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, obstetrician-gynecologists should advocate that emergency contraception be easily available and accessible at all times to all women for whom it is not medically contraindicated.
- 3. Emergency contraception is not medically appropriate as an ongoing contraceptive method. Obstetrician-gynecologists have the professional responsibility to ensure that accurate information is available regarding emergency contraception, as well as to discuss future strategies for individuals to avoid the need for emergency contraception.
- 4. 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, July 2017 revision of 2002 version

#### Citation for 2002 version:

Cain JM, FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines regarding privacy and confidentiality in reproductive medicine. Testing for genetic predisposition to adult onset disease. Guidelines in emergency contraception. *Int J Gynecol Obstet* 2002;77:171–175. doi:10.1016/s0020-7292(02)00013-9.

## Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 043: Emergency contraception. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 118–119.

## **Guideline 044: Family Planning**

- 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 childbearing 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 practice family planning.

5. Contraceptive methods provide 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.

- 1. Obstetrician-gynecologists and other healthcare professionals have the professional responsibility to enable and support informed and voluntary decisions about childbearing and use of methods of family planning of an individual's choice, as well as ensure availability of methods for regulation of fertility consistent with applicable law. Professional associations should play a leadership role in ensuring the availability of contraceptive services and ongoing research in this area.
- 2. Prevention of unwanted pregnancies must always be given the highest priority, and every reasonable effort should be made to reduce the incidence of induced abortion. In circumstances in which induced 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 have the professional responsibility to urge wider legal access to services.
- 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. Obstetrician-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 unwanted pregnancy and the emergence of HIV/AIDS and other sexually transmitted infections.
- 5. If a physician or other healthcare professional is either unable or unwilling to provide a desired method of family planning or medical service for nonmedical reasons, he or she has the professional responsibility to achieve appropriate and effective referral.

### London, July 2018 revision of 2008 version

#### Citation for 2008 version:

Milliez J. Ethics in family planning. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2009;106:275–276. doi: 10.1016/j.ijgo.2009.03.047. PMID: 19375701.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 044: Family planning. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 119–121.

## **Guideline 045: Sterilization**

- 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 sterilization is a widely used method of contraception. As with all surgical procedures, there is an ethical obligation to engage the patient in the informed consent process so that her decision is informed and voluntary (see Ethics and Professionalism Guideline 004: Informed Consent). Information for consent includes, for instance, that sterilization should be considered irreversible; that alternatives exist such as reversible forms of family planning; that life circumstances may change, creating the possibility that the patient may later regret consenting to sterilization; and that procedures have a very low but significant failure rate.
- 3. Methods of sterilization generally include tubal ligation or other methods of tubal occlusion. Hysterectomy is inappropriate solely for sterilization because of disproportionate clinical risks and increased financial costs.
- 4. Once an informed choice has been freely made, barriers to surgical sterilization should be minimized. In particular, sterilization 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 counseling; and physicians whose beliefs oppose participation in sterilization should comply with Guideline 014: Conscientious Objection.

- 5. Evidence exists, including by governmental admission and apology, of a long history of forced and otherwise nonconsensual sterilization of women, including Roma women in Europe and women with cognitive disabilities in the United States. Reports have documented the coerced sterilization 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 sterilized without their own freely given, adequately informed consent.
- 6. Obstetrician-gynecologists must recognize 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 a woman's own health interests.
- 7. Women with the capacity to participate in the informed consent process should provide authorization for their own sterilization. Family members—including husbands, parents, legal guardians, medical practitioners and, for instance, government or other public officers—cannot consent for a patient with the capacity to participate in the informed consent process.
- 8. Women's consent to sterilization should not be made a condition of access to medical care—such as HIV/AIDS treatment, vaginal or cesarean delivery, or induced abortion—or of any benefit such as medical insurance, social assistance, employment, or release from an institution. In addition, the informed consent process for sterilization should not occur when women may be vulnerable, such as when requesting termination of pregnancy, going into labor, or in the aftermath of delivery.
- 9. It is unethical for medical practitioners to perform sterilization procedures within a government program or strategy that does not include informed and voluntary consent to sterilization.
- 10. Sterilization 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 nonemergency 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 sterilization must be considered a permanent, irreversible procedure that prevents future pregnancy and that nonpermanent alternative treatments exist. It must also be emphasized that sterilization 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 should reasonably be expected to understand, and in an accessible format such as sign language, Braille, and plain nontechnical language appropriate to the individual woman's needs. The physician performing sterilization 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 United Nations Convention on the Rights of Persons with Disabilities [1] 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 recognized;
  - b. The rights...to decide freely and responsibly on the number and spacing of their children...are recognized, 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."

- 1. No woman may be sterilized in the absence of her informed and voluntary consent. The use of coercion, pressure, or undue inducement by healthcare providers, institutions, or the state is ethically impermissible.
- 2. Women considering sterilization 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 nontechnical language appropriate to the individual woman's needs. Women should also be provided with information about medically reasonable nonpermanent options for contraception. Misconceptions about prevention of sexually transmitted diseases (STDs), including HIV, by sterilization need to be addressed with appropriate counseling about STDs.
- 3. Sterilization 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 sterilization entails and to make her choice known.
- 4. Consent to sterilization 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 sterilization constitutes an act of criminal violence, whether committed by individual practitioners or under institutional or governmental policies. It is ethically impermissible for an obstetrician-gynecologist to provide forced sterilization.
- 6. It is ethically inappropriate for healthcare providers to initiate judicial proceedings for sterilization of their patients, or to be witnesses in such proceedings inconsistently with Article 23(1) of the United Nations Convention on the Rights of Persons with Disabilities [1].
- 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 informed consent or medically reasonable provision of sterilization.

### References

[1] United Nations. Convention on the Rights of Persons with Disabilities (CRPD). https:// www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-withdisabilities.html. Accessed June 12, 2021.

## London, July 2019 revision of 2011 version

## Citation for 2000 version:

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## Citation for 2020 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 045: Sterilization. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 121–125.

# Guideline 046: 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 identification before birth of an increasing number of conditions known to severely affect the neonate. These methods include preimplantation genetic diagnosis (PGD), fetal DNA screening in maternal blood, chorionic villus sampling, serum biochemical screening tests for Down syndrome or neural tube defect, amniocentesis, and cordocentesis. Diagnostic tools include molecular biology, such as polymerase chain reaction (PCR), molecular genetics, fluorescence in situ hybridization (FISH) for rapid chromosomal defects detection, chromosomal micro satellite analysis, high-definition fetal imaging with ultrasound, Doppler, MRI, helicoid scanner, or fetoscopy. Genome sequencing of fetal material should be considered investigational, because its biological, psychological, and social outcomes for the women, the genetic father, their genetic kin, and the future child are not known.

- 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 postnatal therapy or may lead to termination of pregnancy. Clearly PGD may avoid more difficult choices and, as appropriate, should be offered as a reproductive option.
- 3. Delivering and raising a baby with a severe congenital disease or disorder 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 to be unacceptable to them. For both reasons there is a professional responsibility to explain clearly the results of prenatal evaluation and their implications.
- 4. Cultural, religious, or personal beliefs may require women and couples to oppose prenatal therapy or refuse abortion. For instance, Jehovah's Witnesses may deny intrauterine blood transfusion for their anemic 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. These cultural, religious, and personal beliefs vary enormously among women.
- 5. Legal regulations on 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 legalize abortion up to the limit of "fetal viability", usually 24 weeks; others accept termination of pregnancy for fetal disease up to full term.
- Induced abortion practiced at mid-term and later has the potential of leading to premature live birth. Provisions that ensure a stillbirth are usually practiced for fetuses undergoing an abortion beyond 22 weeks of gestation. These provisions may be subject to legal regulation.
- 7. In some countries, 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. Another component of the judgment of severity is the parents' capacity to cope with the child's condition and its effect on their family.
- 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 an abortion may be decided only because of a high risk, but not a certitude, of less severe conditions, 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 subsequently confirmed, may remain of unknown clinical consequence, and incline parents to request a termination of pregnancy. Due to the potential complexity of their indications, no normative list of diseases deemed to justify abortion has been established, leaving the decision to each individual case based on respect for the autonomy of the pregnant woman.

- 9. In most countries where termination of pregnancy for fetal disease is accepted, prenatal diagnosis is directed to specialized multidisciplinary centers, including obstetricians, pediatricians, geneticists, pediatric surgeons, pathologists, and psychologists. When appropriate, 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 challenging for prospective parents, who need not only technical advice, but above all full psychological, affective support, and, for those who wish it, spiritual support, including accurate information about the ethics of abortion in their faith community. 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 pain by appropriate precautions or medications. It is possible that fetuses experience the same level of pain as neonates of the same gestational age. Analgesia should be considered for invasive procedures on the fetus. In addition, whenever a parent opts to maintain pregnancy for the severely affected or malformed fetus, all appropriate care, including palliative care, 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, should be engaged in the process of prenatal diagnosis without being fully informed of its aims and limitations and the possible confrontation with a decision about termination of pregnancy. The potential hazard of causing miscarriage from invasive techniques should also be explained, even when the reported rate is very low.

- 2. In countries where it is an accepted medical practice, whenever a severe untreatable fetal disease or condition incompatible with interactive capacity and subsequent development is diagnosed by prenatal diagnosis, termination of pregnancy must be offered to the pregnant woman. However, women and couples must never be compelled to accept abortion, whatever the severity of the fetal condition, if abortion is against their personal, cultural, or religious beliefs. The pregnant woman 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. It must always be clear, however, that final decision-making authority rests with the pregnant woman.
- Prenatal diagnosis and decisions to terminate pregnancy must be restricted to appropriately staffed centers committed to patient safety and quality.
  Pregnant women seeking prenatal diagnosis must receive not only technical advice but also the benefit of full psychological support.
- 4. When termination of periviable pregnancy is legal and when it is ethically justified, the option of feticide (when legally permitted) should be presented to prevent the outcome of live birth. To initiate the mourning process, parents must be encouraged, if they feel strong enough, to be with 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.
- 5. If after prenatal diagnosis parents opt to maintain pregnancy, appropriate care must be offered including a detailed birth plan. This plan should address whether aggressive obstetric management (monitoring, cesarean delivery) will be used and whether the neonate in the case of live birth will be resuscitated and provided neonatal intensive care. If not, the plan should be for obstetric and neonatal palliative and comfort care.

## London, July 2018 revision of 2007 version

#### Citation for 2007 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical aspects concerning termination of pregnancy following prenatal diagnosis. *Int J Gynecol Obstet* 2008; 102:97–98. doi: 10.1016/j.ijgo.2008.03.002. PMID: 18423641.

## Citation for 2018 revision:

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## **Guideline 047: Induced Abortion for Nonmedical Reasons**

- 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 woman 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 pregnant woman'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 agonize over their difficult choice, making what they regard in the circumstances to be the least worst decision. Healthcare 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 nonmedical 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 of the 40 million or more induced abortions performed around the world each year are unsafe because they are undertaken by unskilled persons and/or in an unsuitable environment.
- 7. The mortality following unsafe abortion is estimated to be very many times greater than when the procedure is performed in a medical environment. At least an estimated 75,000 women die unnecessarily each year after unsafe abortion and very many more suffer life-long ill-health and disability, including sterility [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 nonmedical 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 nonmedical 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 popularized 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.
- Neither society, nor members of the healthcare 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 nonmedical reasons is best provided by the healthcare service on a nonprofit-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 healthcare service has an obligation to provide such services as safely as possible.

\*Note: This is not relevant to the lethally malformed fetus, cf Ethical Aspects of the Management of the Severely Malformed Fetus, *Int J Gynecol Obstet* 1996;53:300. It is also important to consider Ethical Aspects in the Management of Newborn Infants at the Threshold of Viability, *Int J Gynecol Obstet* 1997;59:165–168.

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[1] March of Dimes, PMNCH, Save the Children, WHO. Born too soon: The global action report on preterm birth. Eds CP Howson, MV Kinney, JE Lawn. World Health Organization. Geneva, 2012. https://apps.who.int/iris/bitstream/handle/10665/44864/9789241503433\_eng.pdf;jse. Accessed June 21, 2021.

[2] World Health Organization. Unsafe Abortion: Global and Regional Estimates of Incidence of and Mortality due to Unsafe Abortion with a Listing of Available Country Data, 3rd edition, WHO/RHT/MSM/97.16, 1998.

## London, July 2016 revision of 1998 version

#### Citation for 1998 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Gynecol Obstet Invest* 1999;48:73–77.

### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 047: Induced abortion for nonmedical reasons. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 129–132.

## **Guideline 048: Post-Abortion Care**

- 1. Post-abortion care may be required when a woman experiences abortion that is deliberately induced, by the woman herself or by another, or that occurs spontaneously. At a later stage of pregnancy, this may be defined as miscarriage. Deliberately inducing abortion may be lawful or unlawful, depending on locally prevailing laws.
- Physicians bear an ethical responsibility to render prompt assistance to anyone in need of medical care they are able to provide, without discriminating regarding the lawful or other origin of the condition they treat. Much of the mortality associated with induced abortion is due to deficient post-abortion care. Refusal or failure to render care appropriately constitutes professional misconduct.

- 3. Delivery of post-abortion care to professional standards is legitimate, necessary, and does not in itself implicate providers in another's prior illegality or professional misconduct.
- 4. Post-abortion care is legally separate from any procedures that may have been undertaken deliberately to induce abortion. Post-abortion care providers, such as in hospital or clinic emergency or gynecology departments, are ethically required to render indicated care promptly to meet patients' needs, and bear no responsibility for others' prior acts or omissions that caused the need for such care.
- 5. A care provider who has a conscientious objection to participating in inducing abortion cannot invoke such objection to decline rendering clinically indicated post-abortion care. As a provider of post-abortion care, a care-giver is not a participant nor complicit in another's prior acts causing the need of such care.
- 6. Safe management of post-abortion care is a professional skill required of all qualified practitioners of obstetrics and gynecology. Training in the medical specialty requires inclusion of post-abortion care.
- Like delivery of other forms of health care, post-abortion care requires professional regard for patients' physical and psychological or emotional health needs, that is for patients' "physical, mental and social well-being" (World Health Organization meaning of "health") [1].
- 8. Some laws require that care providers report evidence of unlawful termination of pregnancy to law-enforcement authorities. Such laws violate medical professional duties of confidentiality and patients' human rights, and require that providers reliably distinguish spontaneous from induced abortion, and between lawful and unlawful interventions in pregnancy.

- 1. Practitioners should promptly render indicated post-abortion care to patients that is within their means without regard to whether as professionals they conscientiously object to participation in induced abortion.
- 2. Post-abortion care should include emotional support for patients, and be delivered in the same non-judgmental, non-stigmatizing way as other professional gynecologic services.
- 3. On admitting patients to their post-abortion care, practitioners should record whether they have rendered any prior individual professional services to such patients.

- 4. Practitioners should ensure that the facilities in which they are engaged are adequately equipped, for instance with drugs, equipment, and trained personnel, to deliver timely professional care indicated for post-abortion patients, including counseling and advice on birth control and contraception.
- 5. Educational programs and professional certification in gynecology should require training and competence in post-abortion care, disallowing students' and candidates' non-compliance on grounds of conscientious objection to participation or complicity in induced abortion.
- 6. Practitioners and professional associations should oppose and resist laws and proposed laws that compel practitioners to inform law-enforcement authorities of post-abortion patients' identities, on grounds that such laws violate professional ethics and patients' human rights to confidentiality, risk harmful misinformation, are unreliable for professionals to implement, and dysfunctional in not deterring illegality but in deterring patients from promptly seeking indicated, necessary, lawful care.
- Service providers and managers of service facilities should be familiar with and observe the World Health Organization statement *Safe abortion: technical and policy guidance for health systems* [2], especially Section 2.3 on post-abortion care and follow-up.
- 8. Human rights agencies, both national and international, characterize neglect or limitation of health services that only women need as violating obligations to eliminate all forms of discrimination against women. Practitioners and facility managers should ensure compliance with non-discrimination laws in provision of post-abortion care services.

## London, July 2018 (new)

## References

[1] World Health Organization. Constitution of the World Health Organization. Geneva, 2006. https://www.who.int/governance/eb/who\_constitution\_en.pdf. Accessed 21 June, 2021.

[2] World Health Organization. Safe abortion: technical and policy guidance for health systems. Geneva, 2012. https://www.who.int/reproductivehealth/publications/unsafe\_abortion/9789241548434/en/. Accessed 21 June, 2021.

## Citation

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 048: Post-abortion care. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 132–134.

# Guideline 049: Management of Severely Disabled Women with Gynecological Problems

- 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 they may not be able to protect themselves physically. Severely mentally disabled women 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, known as a surrogate decision maker. If a proposed surrogate decision maker appears influenced by a conflict of interest or conflict of commitment, the obstetrician-gynecologist will have to apply independent judgment of the disabled woman's best interests and make recommendations accordingly. In any event, the disabled woman should be involved in the decision to the full extent of her developmental 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 sterilizations have been carried out. This has included women who meet the criteria for independent, autonomous decision making and consent. If they were to be sterilized without their voluntary consent, this would be unethical and a violation of their human rights.
- 5. There are reports of women with severe disability receiving surgical and medical treatments to induce amenorrhea, including irreversible and higher risk surgical approaches such as hysterectomy, without appropriate consent.
- 6. In contrast to involuntary permanent contraception and sterilization, which are conducted without the subjects' true consent and considered human

rights violations, there are contexts where nonvoluntary 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, these 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 ethically and legally permissible to conduct judicially approved procedures.

- 1. It is essential that the general hygienic and other health needs of women with severe disabilities be managed without discrimination, by accepted professional standards of care and management applicable to all women.
- 2. Healthcare professionals should advocate policies that prohibit discrimination on the basis of physical and/or mental disability, and that guarantee equal legal protection to all female and pregnant patients.
- If a woman has diminished capacity to decide on meeting her hygienic and other healthcare needs, surrogate decisions should be made based on the substituted judgment standard, i.e. on the basis of her values and beliefs. If this standard cannot be met, surrogate decisions should be based on the best interests standard of surrogate decision making.
- 4. If a woman has no capacity to decide on meeting her hygienic and other healthcare needs, surrogate decisions should be made in her best interests by her surrogate decision maker(s).
- 5. 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 the legally designated surrogate decision maker with court review when legally required.
- 6. If a woman is too mentally disabled to comprehend menstruation, and evidence shows that each month the experience poses clinically significant psychological distress or she is not able to maintain personal hygiene during menstruation, it is both ethically and medically prudent to recommend the least invasive and appropriate medical or surgical options.
## London, July 2019 revision of 2011 version

#### Citation for 2011 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Ethical issues in the management of severely disabled women with gynecologic problems. *Int J Gynecol Obstet* 2011;115:86–87. doi: 10.1016/j.ijgo.2011.07.003. PMID: 21839450.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 049: Ethical issues in the management of severely disabled women with gynecologic problems. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 135–137.

# **Guideline 050: Caring for Patients After Sexual Assault**

- Sexual assault is a crime of violence against a person's body and autonomy. 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, including children, are the overwhelming majority of victims. Families may also experience psychosocial distress and trauma.
- 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.

- Forensic examinations provide evidence of sexual assaults and facilitate identification, prosecution, conviction, and punishment of offenders. Examinations are for purposes of law enforcement and should be followed by arrangements to meet women's needs of appropriate medical care.
- 5. Forensic testing ranges from nonintrusive 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 United States 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 have been 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, autonomy, 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 Guideline 006: Confidentiality and adolescent patients.
- 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 Guideline 034: Pregnancy and HIV-positive patients. 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 that they find acceptable.
- 13. In addition to training in forensic science, examiners require training in forensic law, including court and judicial processes, in order not to 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. However, such an approach may be subject to sexist prejudice, inasmuch in some jurisdictions 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, especially 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. Dispensing 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 Guideline 014: Conscientious objection, to ensure immediate care of patients who request this treatment.

- On confidentiality of women who have been assaulted and mandatory reporting, see Guideline 052: Public health and policy dimensions of violence against women, and Guideline 053: Clinical dimensions of violence against women.
- 10. Every obstetrician-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.

#### References

[1] World Health Organization. Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: WHO; 2013. Glossary, p. viii. https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/. Accessed July 3, 2019.

[2] U.S. Department of Justice. Office on Violence Against Women. A National Protocol for Sexual Assault Medical Forensic Examinations. Adults/Adolescents. Second Edition, April 2013. NCJ 228119. https://www.ncjrs.gov/pdffiles1/ovw/241903.pdf. Accessed July 3, 2019.

#### London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Ethical issues after sexual assault. *Int J Gynecol Obstet* 2015;128:187–188. doi: 10.1016/j.ijgo.2014.10.007. PMID: 25458412.

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FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 050: Caring for patients after sexual assault. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 137–141.

# Guideline 051: HPV Vaccination and Screening to Prevent Cervical Cancer

## Background

- 1. Cervical cancer is a common cause of death from cancer for women in low-resource countries and for women in high-resource countries who have decreased access to health care, especially screening.
- 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. There is a complementary professional responsibility to protect and promote women's health by providing them effective preventive health care.
- 3. HPV subtypes 16 and 18 are the proximate cause of 70% of cervical cancer worldwide with regional patterns that include multiple other oncogenic subtypes.
- 4. HPV is a sexually communicable disease for which the burden of death and disability falls disproportionately on women.
- 5. Cervical cancer is now a preventable disease through a combination of early vaccination and screening strategies to identify and treat preinvasive disease.
- 6. In order to be effective, the present vaccines to HPV16 and 18 must be given at an age before likely viral exposure, often before commencement of sexual intercourse.

- 1. Physicians should advocate for education of both health professionals and communities about prevention of cervical cancer through both vaccination and screening strategies as part of the professional responsibility 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. Healthcare professionals should be aware of and address parental concerns that vaccination may predispose their daughter to sexual intercourse.
- 5. Development of community/national/NGO/WHO partnerships is needed to create affordability for vaccination and screening programs to prevent cervical cancer.
- 6. Obstetrician-gynecologists have the professional responsibility to advocate for vaccination and screening and to assist in the creation of coalitions of professional associations, nongovernmental organizations, and effective government agencies to address prevention of cervical cancer.

#### London, July 2018 revision of 2007 version

#### Citation for 2007 version:

Milliez J; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. HPV vaccination and screening to eliminate cervical cancer. *Int J Gynecol Obstet* 2008;101:216–217. doi: 10.1016/j.ijgo.2008.02.003. PMID: 18339392.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 051: HPV vaccination and screening to prevent cervical cancer. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 142–143.

# Guideline 052: Public Health and Policy Dimensions of Violence Against Women

## Background

1. Violence against women is multifaceted 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.

- 1. Violence against women is condemned, whether it occurs in a societal setting (such as female genital mutilation) or a domestic setting (such as partner abuse or rape). 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 recognize cases. Documentation must take into account the need for confidentiality to avoid potential harmful consequences for the woman, which may require separate, nonidentifiable 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.
- The physical, financial, and social vulnerabilities of women are fundamentally harmful to the future of any society. Violence against women is a crime. Not redressing these vulnerabilities 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, honor killings, and sex selection.
  - ii. Advocate for nonviolent resolutions of conflicts in relationships by enlisting the aid of social workers and other healthcare professionals where appropriate.
  - iii. Make themselves, and others, aware of the harmful effects of the embedded discrimination against women in social systems.
  - iv. Advocate for appropriate legislation that criminalizes violence against women and provides protection for women who are victims of violence and their children.
  - v. Advocate for effective enforcement of applicable law so that when women report violence the criminal justice system will respond.
- There is a need for wider awareness of the magnitude of the problem of violence against women. Only if this problem is recognized 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.

#### London, July 2018 revision of 2008 version

#### Citation for 2008 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Violence against women. *Int J Gynecol Obstet* 2008;102:95–96. doi: 10.1016/j.ijgo.2008.03.003. PMID: 18436223.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 052: Public health and policy dimensions of violence against women. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 143–145.

# Guideline 053: Clinical Dimensions of Violence Against Women

- The United Nations defines violence against women as "any act of genderbased 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"
   This may also include verbal violence such as insults, threats, shouted commands, or condemnation or silence that can result in stress.
- 2. The range of violent conduct that women experience should not be underestimated and can have serious clinical consequences, especially to pregnant women. 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 World Health Organization (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. Violence against women should be considered an 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 obstetriciangynecologists. 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-birthweight babies. Violence can also increase the risk of suicide, especially in adolescent women.
- 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 clinical 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 professionals ill-equipped to deal effectively with patients victimized by domestic, stranger-initiated, or other violence.

- 7. Despite healthcare professionals' 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 professionals 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. Obstetrician-gynecologists may be preferred because they may examine patients in privacy, in the absence of, for instance, husbands, mothers-in-law, or any other family members. Obstetrician-gynecologists therefore have the professional 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, obstetrician-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 caregivers 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

 Member societies of FIGO should support the prequalification and postqualification training of all relevant healthcare professionals, particularly obstetrician-gynecologists, midwives, and nurses, in the 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 from national associations of obstetrician-gynecologists and other professional associations of physicians.

- 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 clinical 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 professionals.
- 3. When women disclose violence, healthcare professionals should assess their conditions, asking questions when necessary to improve the diagnosis and women's immediate and subsequent conditions, and improve clinical management of these conditions. Clinical care should be womancentered, with clinicians offering support that includes consultation in private, protected by the professional obligation of confidentiality, being nonjudgmental, and validating patients' narratives through careful, respectful listening. Enquiries about their experience of violence should not pressure women to talk, aim to increase safety for patients and their children when needed, and help patients to access available resources. Interpreters should be bound by the same professional obligation of confidentiality as physicians and this ethical requirement should be made explicit and consent to it documented during the hiring and training processes.
- 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 professional care. Healthcare professionals 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 termination of pregnancy 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 Guideline 014: Conscientious objection, to ensure timely treatment on patients' requests.
- 7. Healthcare professionals should also be prepared to provide or refer to 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 healthcare professional administered.

- 8. Laws mandating reporting evidence of violence have to be followed, but otherwise healthcare professionals 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, obstetriciangynecologists should advocate their reconsideration or revision.

#### London, July 2019 revision of 2014 version

#### References

[1] United Nations. General Assembly. A/RES/48/104. Declaration on the elimination of violence against women. 1993. https://www.ohchr.org/en/professionalinterest/pages/violenceagainstwomen.aspx. Accessed July 3, 2019.

[2] World Health Organization. Violence against women: Intimate partner and sexual violence against women. Key Facts, 2021. http://www.who.int/mediacentre/factsheets/fs239/en/.Accessed July 3, 2019.

[3] World Health Organization. Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: WHO; 2013. Glossary, p. viii. https://www.who.int/reproductivehealth/publications/violence/9789241548595/en/. Accessed July 3, 2019.

#### Citation for 2014 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health; International Federation of Gynecology and Obstetrics. Ethical guidance on healthcare professionals' responses to violence against women. *Int J Gynecol Obstet* 2015;128:87–88.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 053: Clinical dimensions of violence against women. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 145–149.

# **Guideline 054: Female Genital Cutting**

- 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 becoming increasingly illegal throughout the world, this has not reduced the number of girls affected every year. Currently, most governments across the world do not appear to be 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 FGC controls women's sexual and reproductive function, beliefs about cleanliness and hygiene, and belief that FGC promotes virginity and chastity and enhancement of male sexual pleasure.
- 6. The assertion that religion requires this procedure is refuted by many religious leaders inasmuch as most faith communities, including Islam, forbid physical violation of the human body. The sacrifice of individual health and welfare to promote merely cultural beliefs is of no benefit to communal wellbeing.
- 7. As affirmed in the FIGO resolution of 1994 in Montreal [1], FGC is ethically impermissible, because it violates the physician's professional responsibility to protect and promote the biopsychosocial health of female patients as well as well-established human rights principles, including the human rights of bodily integrity and self-determination.

- 8. Respect for patient 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 for their parents' beliefs, which requires that they receive special protections.
- 9. Medicalization of FGC is not permissible, even if it may reduce the immediate health hazards of the procedure. However, medicalization may promote underestimating its overall physical and psychological complications, and still offends ethical principles and human rights, particularly the rights of the child. It creates tacit approval supporting this cultural practice, rather than disapproving such behavior and encouraging change in behavior.
- 10. 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.
- 11. FGC is an irreparable, irreversible abuse of the female child.
- 12. FGC violates all ethical principles in the professional ethics of obstetrics and gynecology. Physician provision of any aspect of FGC is therefore ethically impermissible.

- 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. Physicians should advocate for prohibition of practices that are biologically, psychologically, and socially harmful, which can be accomplished without giving up meaningful aspects of a culture.
- 2. Physicians should advocate for 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. This is one effective step toward eradication of FGC.
- 3. Physicians should forge effective 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. This is another step toward eradication of FGC.

- 4. Eradication of FGC requires cooperation at the national and international levels, for which FIGO leadership should advocate.
- 5. United Nations agencies (including UNICEF, UNFPA, WHO), FIGO, and other agencies active in this area have already taken steps toward abolishing this practice. Member societies of FIGO should join FIGO and international bodies in issuing firm guidelines that prohibit their members from participating in this practice.
- 6. Women of all ages who have been subjected to FGC should be treated with sympathy, respect, and medical evidence-based care. After childbirth, if suturing is needed, it is preferable to restore the anatomy to the noninfibulated state. When legally permitted, properly informed women who have been infibulated who, following childbirth, independently request restoring the anatomy to the infibulated state may be accommodated.
- 7. FGC by healthcare professionals should be condemned at all national and international levels. It is the duty of professional bodies and organizations to advise members and all health professionals not to undertake FGC, and to hold them accountable for this unethical practice.

## Reference

[1] FIGO. Against the medicalisation of FGM/C. https://www.figo.org/news/againstmedicalisation-fgmc. Accessed June 21, 2021.

## London, July 2018 revision of 2006 version

## Citation for 2006 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health; FIGO Committee on Women's Sexual and Reproductive Rights. Female genital cutting. *Int J Gynecol Obstet*. 2006;94:176–177. doi: 10.1016/j.ijgo.2006.06.008. PMID: 16844122.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 054: Female genital cutting. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 150–152.

# **Guideline 055: Cosmetic Genital Surgery**

## Background

- In professional ethics in obstetrics and gynecology, cosmetic medical or 1 surgical intervention should satisfy four criteria, in order for them to be considered ethically permissible: (a) there is no pathology present. This means that there is no medical indication for the procedure; (b) the procedure has clinical validity in that there is an evidence base for its efficacy and safety; (c) there is an evidence base for the minimization of the complications and risks of the procedure required by beneficence-based clinical judgment; (d) the indication for the procedure is the informed and voluntary consent of the patient. The informed consent process should include information about the biomedical risks but also its psychosocial risks, including the risk that the patient may become unsatisfied with results. The informed consent process should therefore include information about whether there are valid procedures to modify or reverse the cosmetic alteration of the patient's anatomy and physiology, as well as the psychosocial risk that the patient may judge results of cosmetic procedures to be unsatisfactory.
- 2. There is no clear evidence for the effectiveness and safety of cosmetic genital surgery. This means that the second criterion for ethically permissible cosmetic surgery is not satisfied.
- 3. It follows that it is ethically impermissible for an obstetrician-gynecologist to offer, recommend, perform, or refer for cosmetic genital surgery.

- 1. Obstetrician-gynecologists should not offer, recommend, perform, or refer for cosmetic genital surgery.
- 2. If a patient expresses an interest in or requests cosmetic genital surgery, the patient's understanding of cosmetic genital surgery should be explored respectfully. The obstetrician-gynecologist should explain that there is no clear evidence of effectiveness or safety and that, for this reason, he or she is recommending against it.
- 3. Taking this approach will prevent unmanageable economic conflicts of the interest on the part of the obstetrician-gynecologist.

## London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health; FIGO Committee on Women's Sexual and Reproductive Rights. Female genital cutting. *Int J Gynecol Obstet* 2006;94:176–177. doi: 10.1016/j.ijgo.2006.06.008.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 055: Cosmetic genital surgery. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021:153–154.

## Guideline 056: Women's Post-Reproductive Lives

- The ovary contains a finite number of oocytes that decreases 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, and 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. For example, children may have grown up and left the household.
- 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. The biopsychosocial concept of health and

disease rejects this biomedical reductionism as scientifically and clinically inadequate. From this perspective menopause should be considered a normal, life-change transition with positive aspects and gain for women, with some experiencing clinical complications that should be assessed and managed biopsychosocially, taking into account clinically significant biological, psychological, social, and cultural factors. A holistic approach is therefore appropriate.

- 4. The management of menopausal transition should be informed by recent scientific evidence. 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 professionals. 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. Obstetrician-gynecologists should explain that it is normal for scientific evidence to change, resulting in changing recommendations. Each patient should be assured of the commitment of her obstetrician-gynecologist to identify and recommend evidence-based clinical management of menopause.
- 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. Healthcare professionals are sometimes 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-income countries make it difficult for women with limited economic resources to access appropriate healthcare programs.

- 1. Leaders of healthcare organizations and government agencies should ensure that adequate resources are 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, the biopsychosocial challenges that may arise, and how they can be managed.
- 3. Member societies should act as advocates for women and advocate for the 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 professionals should undergo training to ensure that they can provide proper care for the clinical challenges that some postmenopausal women may face. 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 professionals should be proactive in initiating discussion of menopausal symptoms especially in the area of sexual problems, irrespective of their personal beliefs, as women may feel embarrassed to initiate discussion on intimate topics.
- 6. Healthcare professionals should ensure that they are familiar with the most updated information including the evidence-based guidelines on menopausal problems and their management.

7. In scientific discourse and public health education, healthcare professionals should provide accurate, evidence-based information. If there is any potential for conflict of interest, it should be declared (see Guideline 011: Responsibly managing conflicts of interest in clinical practice and research).

#### References

[1] Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA* 2002;288:321–333.

[2] Hulley S, Grady D, Bush T, et al. Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. Heart and Estrogen/progestin Replacement Study (HERS) Research Group. JAMA 1998;280:605–613.

[3] de Villiers TJ, Hall JE, Pinkerton JV, et al. Revised global consensus statement on menopausal hormone therapy. *Maturitas* 2016;91:153–155.

#### London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for Ethical Aspects of Human Reproduction and Women's Health. Ethical issues in women's post-reproductive lives. *Int J Gynecol Obstet* 2015;128:189–190. doi: 10.1016/j.ijgo.2014.10.008. PMID: 25458413.

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 056: Women's post-reproductive lives. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 154–157.

## Guideline 057: Health Care of Sex Workers

## Background

 Human rights to nondiscrimination and equality underpin the entitlement of all women, regardless of health, social, or economic status, to medically indicated care and to receive treatment nonjudgmentally and with dignity. Sex workers should therefore receive appropriate care without discrimination

- 2. Guideline 001: Professionalism in obstetric and gynecologic practice emphasizes that justice requires that all female patients should be treated with equal consideration, irrespective of their socioeconomic status.
- 3. Guideline 015: Harmful stereotyping of women in health care requires that obstetrician-gynecologists become 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 nonjudgmental, 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. When 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.

- 1. Obstetrician-gynecologists should respond to requests for care by women disclosing sex work occupations nonjudgmentally and without discrimination, for instance by not separating them from other patients. Infection control should be the same as for any patient.
- 2. When patients disclose subjection to sexual or other violence, practitioners should observe Guideline 053: Clinical dimensions of violence against

women. Obstetrician-gynecologists should be vigilant in detection of signs of violence in such patients.

- 3. Obstetrician-gynecologists 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 applicable law, practitioners should observe 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. The obstetrician-gynecologist 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 the professional responsibility to educate their members about the rights of sex workers to nondiscrimination 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.

## London, July 2019 revision of 2015 version

## Citation for 2015 version:

Dickens B; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical health care of sex workers. *Int J Gynecol Obstet* 2016;133:245–246. doi: 10.1016/j.ijgo.2016.02.001. PMID: 26961587.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 057: Health care of sex workers. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 157–159.

# Guideline 058: Genetic and Genomic Testing for Risk Assessment of Adult-Onset Disease

## Background

- Genetic testing can be used to diagnose conditions, estimate reproductive risk, estimate the risk of future conditions, and plan medication (pharmacogenomics). Genetic testing also produces results of uncertain clinical significance.
- 2. Risk assessment for future conditions is not diagnostic.
- 3. It is possible to estimate risk of adult-onset conditions by testing children who are legal minors, fetuses, and embryos.
- 4. There is strong consensus that genetic/genomic risk assessment of nonadults for adult-onset conditions for which there is no effective prevention before adulthood assessment should be postponed until the individual becomes an adult and can consent to such risk assessment for himself or herself.
- 5. It is ethically permissible to perform genetic/genomic risk assessment of nonadults for adult-onset conditions for which there is effective prevention before adulthood, given the professional responsibility to provide patients with effective preventive measures.
- 6. There is controversy about the existence and extent of a professional responsibility to disclose results of uncertain clinical significance.

- 1. When genetic/genomic risk assessment is ethically permissible, it should be undertaken only with the informed consent of the patient, the patient's parents, or the pregnant woman.
- 2. In this informed consent process, it is essential that the decision maker understand that genetic/genomic analysis may produce unexpected results of clinical significance and that there is a professional responsibility to disclose such results and a treatment plan for them.
- In this informed consent process, it is essential that the decision maker understand that genetic/genomic analysis may produce unexpected results of uncertain clinical significance and the patient is free to refuse disclosure of such results.
- 4. There is professional responsibility that the clinician leading the informed consent process is qualified by training and experience to do so. It is agreed

that only physicians and other healthcare professionals, such as genetic counselors, meet this requirement in the context of genetic/genomic analysis. The obstetrician-gynecologist should therefore refer the patient who is a candidate for such analysis to such a healthcare professional.

## London, July 2017 revision of 2001 version

#### Citation for 2001 version:

Cain JM; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines regarding privacy and confidentiality in reproductive medicine. Testing for genetic predisposition to adult onset disease. Guidelines in emergency contraception. *Int J Gynecol Obstet* 2002;77:171–175.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 058: Genetic and genomic testing for risk of adult-onset disease. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 160–161.

# Guideline 059: The Use of Anti-Progestins

- 1. Patients have the right to enjoy the benefits of new scientific knowledge and there is a professional responsibility to inform them.
- 2. Anti-progestin drugs are a safe and effective method for the medical termination of pregnancy.
- 3. In countries where anti-progestins have been made available, this 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.

## Recommendations

1. Obstetrician-gynecologists should advocate for the availability of antiprogestins for the medical termination of pregnancy.

## London, July 2016 revision of 1994 version

## Citation for 1994 version:

FIGO Committee for the Study of the Ethical Aspects of Reproductive Medicine and Women's Health. Ethical considerations respecting the use of anti-progestins. In: *Ethical Issues in Obstetrics and Gynecology*. London: FIGO; 2015: 128.

## Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 059: The use of anti-progestins. In Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 161–162.

# **Guideline 060: Care of Terminally III Patients**

## Background

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

- 1. The healthcare professional should first clarify what goals of medicine can be met in the terminal phase of illness, such as relief of suffering and pain and the maximization of comfort. These factors take precedence when the goals of cure or remission are no longer obtainable.
- The transition from curative to palliative care where possible may require the primary involvement of physicians with special knowledge of palliative care. The obstetrician-gynecologist should continue his or her supportive role for the patient and her family.
- 3. 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.

- 4. 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.
- 5. Advocacy for adequate terminal care is an important role for women's healthcare 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.
- 6. The patient's care should take into account the potential 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 healthcare provider, must be avoided.
- 7. 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 (see Guideline 033: Intrapartum interventions for fetal well-being).
- 8. 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 to include family and friends in the dying process.
- 9. 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.
- 10. 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 by the physician to deliberately cause death is ethically unacceptable.

#### London, July 2016 revision of 1999 version

#### Citation for 1994 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. International Federation of Gynecology and Obstetrics. *Int J Gynecol Obstet* 1999;66:301–303.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 060: Care of terminally ill patients. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 162–164.

## **Guideline 082: Menstrual Hygiene Management**

- 1. Menstrual hygiene management (MHM) has been defined as "women and adolescent girls using a clean menstrual management material to absorb and collect blood, that can be changed in privacy as often as necessary for the duration of the period, using soap and water for washing the body as required and having access to facilities to dispose of used menstrual management materials"[1].
- 2. FIGO has always held sexual and reproductive health and rights (SRHR) of women around the world as high priority issues. MHM is an important ingredient of SRHR, because it has huge impact on development on the life of girls and women, not only on health but education, security, and gender equality. In the last 10 years MHM rightly has become a globalized public health topic. FIGO seeks to provide global ethical guidance on this vitally important subject.
- 3. In many low- and middle-income countries (LMICs), where girls receive very limited puberty guidance, and the cost of mass-produced sanitary materials is high, the inadequacy (or complete lack) of safe, private, clean water,

sanitation, and disposal facilities creates substantial additional environmental barriers to MHM.

- 4. The lack of proper sanitation facilities and proper and affordable hygiene materials for use by adolescent girls and women at home, at school, and at workplaces affects their health, their potential to access education, employment, overall safety, and quality of life.
- 5. Unsafe and unhygienic materials to absorb menstrual blood can lead to vaginal infections, with possible long-term effects on reproductive health.
  - Psychosocial effects: Menstruation is often associated with shame and disgust, resulting in negative attitudes. Restricting sociocultural practices surrounding menstruation is common. In many LMICs women are practically treated as being "impure" and "untouchable." In some instances, because they have to stay outside their homes, in so-called "menstrual huts," they have suffered and even died due to snake bites and so on. In conservative religious countries, like India, they are not allowed to enter many religious places during menstruation. They are even made to desist from taking part in household religious ceremonies.
  - Education: In many cases, girls will not attend school for the duration of their periods. This is particularly evident in schools with inadequate water, sanitation, and hygiene (WASH) facilities [2,3]. In most LMICs, especially in village schools, due to lack of privacy and wash facilities girls do not attend schools during menstrual periods. In many places they are made to cease their education once they start their menses.
  - Productive work time: Women will be constrained to pursue and maintain employment when they are not able to manage their menstruation hygienically and in privacy at work [4]. Among the contractual workers working in the paddy fields in India, it was a common practice to seek hysterectomy to avoid missing wages during menstruation.
  - Environment: With lack of or limited waste management, non-reusable and commercial items are often disposed of directly into the environment.
- 6. Although menstruation remains a socially stigmatized condition in most contexts, and one that is infrequently discussed in coeducational (or even female-only) encounters, a girl or woman's menstruating status can easily be hidden in high-resource contexts, which is unfortunately not so in low-resource situations.
- 7. In emergency/humanitarian crisis situations, e.g. refugees during war time or immigration crises, women and girls are particularly vulnerable. MHM is

often not properly addressed, resulting in many women and girls confronting barriers to access adequate hygienic and absorbent menstrual materials and WASH facilities or the absence of these resources.

8. Well-designed, culturally competent, and adequately funded research is needed to provide an evidence base regarding the positive overall effects on society and economic development based on of the provision of proper MHM.

## **Ethical framework**

1. The ethical principle of beneficence in professional ethics in obstetrics and gynecology creates the prima facie ethical obligation of the obstetrician-gynecologist to identify and provide clinical management of the patient's condition or diagnosis that, in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment, is predicted to result in net clinical benefit. Such clinical management is known as medically reasonable.

- 1. MHM is a concern not only for women, but for women and men equally, and for societies. FIGO member societies should invoke the ethical principles of beneficence and healthcare justice to advocate for the development of coordinated health policy by all levels of government, to support the development and implementation of effective MHM programs. Health policy should be country-specific and culturally competent. In countries with high awareness concerning reproductive health, it might be most effective to address MHM directly. In other settings it might be most effective to start approaching MHM indirectly from the WASH sector. While implementing a standard around gender/MHM-friendly infrastructure is possible, the design of interventions and policies needs to take into account important factors such as local cultural practices, different needs of different age groups etc.
- 2. FIGO member societies should invoke the ethical principles of beneficence and healthcare justice to advocate for effective international efforts in public health emergencies and humanitarian crisis situations, where women and girls should have access to appropriate resources, which should include:
  - Provision for discreet laundering or disposal of menstrual hygiene materials.
  - Adequate access to water and soap for daily hygiene as well as for the increased needs during menstruation.

- 3. FIGO member societies should invoke the ethical principles of beneficence and healthcare justice to advocate for the evidence-based development and deployment of culturally competent, effective programs that provide medically reasonable MHM to women and girls. There is a growing body of research, particularly around knowledge, attitudes, and practices. However, some of the gaps are:
  - Health effects of poor MHM, health risks associated with the use of certain products and certain practices.
  - Socioeconomic impacts of product donation/tax reduction programs.
  - Product standards and new sustainable and affordable innovations.
  - Effectiveness and standards for different low-cost disposal options.

#### Virtual Meeting from New York, July 2020

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# VII. Clinical Practice of Neonatology

## **Guideline 061: Neonatal Screening**

- 1. All high-income countries have instituted newborn screening (NBS) programs, while some lower-income countries have not done so.
- 2. The aim of NBS is to prevent nontreatment of newborns with serious, treatable disorders that can be ameliorated by early intervention. The condition sought should be an important health problem, and there should be an accepted treatment for patients with recognized disease as well as availability of facilities for diagnosis and treatment. The priority should be on conditions that are severe, frequent, and amenable to easy, safe, reliable, and inexpensive laboratory diagnosis on a very large scale. Whether to include new forms of screening, such as genomic technology, should be evaluated on this basis.
- 3. The principle of respect for patient autonomy embodies the right of parents to have informed choice about screening procedures, but on the other hand, the World Health Organization (WHO) considers that NBS "should be mandatory and free of charge if early diagnosis and treatment will benefit the newborn" [1]. 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 programs are poorly described and probably vary markedly. NBS programs are ethically acceptable when they

are evidence based, take into account the opportunity cost of the program, distribute the costs and benefits of the program fairly, and respect human rights.

- 1. The benefit-to-harm ratio must be favorable whenever a screening program 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. Obstetrician-gynecologists have the professional responsibility to become 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 programs have an obligation to inform all parents about sample retention and to have policies for the use of an identified sample after completion of the screening tests. The role for parental consent should be explicitly stated. Specific consent for sample retention for research must be subject to separate consent related to the long-term uses and implications of research. Failure to have such policies risks loss of trust in NBS, one of the most successful public health programs.
- 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. Obstetrician-gynecologists have the professional responsibility to inform all pregnant women about NBS programs that are available and address any concerns that the pregnant woman may express.
- 6. Obstetrician-gynecologists have the professional responsibility to 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 amongst other health priorities.

## Reference

[1] World Health Organization. Newborn and infant hearing screening. https://www.who. int/blindness/publications/Newborn\_and\_Infant\_Hearing\_Screening\_Report.pdf?ua=1. Accessed June 21, 2021.

## London, July 2018 revision of 2008 version

## Citation for 2008 version:

Milliez J; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical aspects concerning neonatal screening. *Int J Gynecol Obstet* 2009;106:273–274. doi: 10.1016/j.ijgo.2009.03.048. PMID: 19368918.

## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 061: Neonatal screening. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 168–170.

# **Guideline 062: Cord Blood Banking**

- 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 versus 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 or 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. This is required by the best interests of the child in professional ethics in pediatrics.
- 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 toward the potential but unlikely benefit for the developing child. In particular, stressing the potential use for a future child of human leukocyte antigen (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. Public cord blood banks are available to any patient who is an appropriate match. Private cord blood banks do not have this significant clinical and public health advantage. Prospective parents may be unaware of this difference. Because of this difference, public cord blood banking should be considered the medically reasonable option.
- 7. 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.
- 8. Storage of cord blood may also expand the availability of rare HLA groups for the purpose of transplantation.

## Recommendations

- 1. When prospective parents express an interest in cord blood banking, the obstetrician should engage them in the informed consent process. When available, the option of public cord blood banking should be presented as the medically reasonable option, because of its clinical and public health advantages.
- 2. If an obstetrician receives payment for private cord blood banking, that payment should be based on reasonable costs, in order to minimize the potential influence of the resulting economic conflict of interest.
- 3. If prospective parents express an interest in private cord blood banking, the obstetrician should explain the limitations of this option. If the obstetrician is to receive a payment, this should be explained to the prospective parents as a way to responsibly manage the obstetrician's economic conflict of interest.
- 4. The timing and method of cord blood collection should be based on the ethical obligation to prevent harm to the newborn. Early cord clamping for the purpose of collecting cord blood should therefore not be done if there is a risk of childhood anemia. Any contract inconsistent with this ethical obligation should be refused.
- 5. If practitioners decline to undertake cord blood collection owing to the pressure of workload in their units, they may recommend other units where collection is routinely practiced under safe conditions.
- 6. Obstetrician-gynecologists should advocate for support for public cord blood banking, 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, July 2019 revision of 2012 version

## Citation for 2012 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on cord blood banking. *Int J Gynecol Obstet* 2013;120:208–209. doi: 10.1016/j.ijgo.2012.10.003.

## Citation for 2020 revision

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 062: Cord blood banking. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 170–172.
# **Guideline 063: Resuscitation of Newborns**

- According to the United Nations 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, color, 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, color, disability, or ethnicity.
- 3. There may be 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 prenatal 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 centers before delivery.
- 8. Survival and outcome of extremely preterm neonates are critically dependent on gestational age, birth weight, sex, singleton versus multiple, and administration of steroids. Long-term follow-up studies of extremely preterm infants have demonstrated a substantial incidence of neurological,

cognitive, and behavioral problems in survivors. However, in published studies, the majority of adolescent and adult survivors have assessed their quality of life favorably.

- 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.

- 1. There is a professional responsibility to treat newborn infants with the same consideration and respect due to any patient. 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 clinically irrelevant factors, such as religious, demographic, cultural, 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 on 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 professional responsibilities 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 resuscitation or to discontinue treatment.
- 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, a trial of management to be periodically evaluated, until the clinical progress

of the infant, and consultation between an experienced member of staff and the parents, clarify whether it is ethically permissible to discontinue intensive care.

- 7. Medical staff have the professional responsibility to keep parents informed about the likely clinical outcome resulting from the decisions about clinical management and the evidence base for this clinical prognostic judgment.
- 8. The doctor counselling the withholding or withdrawal of medical treatment should be experienced, and seek consultation from pediatric subspecialists when needed, or an Ethics consultant or Committee. The doctor should discuss the problem and the management plan with other members of the healthcare team, including the nursing staff, and address potential disagreement and how it should be responsibly managed.
- 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 as a trial of management 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 palliative care, including, 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. These goals can be facilitated by a neonatal hospice, where it is available.
- 12. After death following the withholding or withdrawal of medical treatment, the medical team has the professional responsibility to request parental consent for autopsy 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. If parents, especially for religious beliefs about inappropriate treatment of the cadaver, refuse invasive examination and if imaging examination is clinically useful, they should be asked to consider noninvasive postmortem examination.

- 13. Obstetrician-gynecologists and their member societies and neonatal societies have the professional responsibility to advocate for the importance of establishing integrated perinatal centers, together with regional organization of perinatal care. The importance of these centers in reducing mortality and morbidity should be highlighted. Continued professional training of all personnel involved in resuscitation and immediate neonatal care is mandatory.
- 14. Obstetrician-gynecologists and their member societies and neonatal societies have the professional responsibility to advocate for close monitoring and record-keeping of perinatal care, and maintain records of all births and their outcome on a regional basis.

#### References

[1] UN General Assembly. Convention on the Rights of the Child. 20 November 1989, United Nations, Treaty Series, vol. 1577, p. 3. https://www.ohchr.org/en/professionalinterest/pages/crc.aspx. Accessed June 21, 2021.

#### London, July 2018 revision of 2006 version

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## Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 063: Resuscitation of newborns. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 173–176.

# **Guideline 064: Management of Infants with Severe Anomalies**

1. Newborn infants with severe anomalies 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. Active euthanasia is ethically unacceptable. However, the withholding or withdrawal of medical care (for example artificial ventilation, antibiotics, nasogastric 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 pain, distress, and suffering is considered appropriate provided that their primary aim is not to cause death.
- 3. The individual decision to withhold or withdraw medical treatment 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.
- 4. Prior to discussing the possibility of withholding or withdrawing medical treatment, the medical team has a responsibility to fully investigate and document the status of the infant and to counsel the parents on their baby's condition and prognosis and on the management options.
- 5. However, when an 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 professional judgement 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.
- 6. Usually, the doctor counselling the withholding or withdrawal of medical treatment 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 healthcare team, including the nursing staff.
- 7. 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.
- 8. 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.
- 9. When there are two parents, but they do not agree with each other as to whether or not to withhold or withdraw treatment, it 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 for judicial decision.

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

## London, July 2016 revision of 1996 version

## Citation for 1996 version:

FIGO committee guidelines. Report of the FIGO committee for the study of ethical aspects of human reproduction. International Federation of Gynecology and Obstetrics. *Int J Gynecol Obstet* 1996;53:297–302.

## Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 064: Management of infants with severe anomalies. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 176–178.

# VIII. Innovation, Research, and Scholarship

# Guideline 065: Inclusion of Women of Reproductive Age in Research

- 1. 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 for which they are or should be clinically eligible.
- 2. 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 may unreasonably question a woman's ability to make informed choices about fertility while on a clinical trial, reducing her rights to make choices about health care, reproduction, and participation in clinical trials.
- 3. Women's decisions should be informed by the physician's evidence-based judgment about the risk of teratogenicity, including an evidence-based clinical judgment about whether teratogenic risk is clinically unacceptable. This information may include an evidence-based clinical judgment that teratogenic risk is clinically unacceptable and that therefore women of childbearing age

are justifiably excluded from a trial. Such a judgment is not an unjust limitation on a woman's right to health care, because research is investigational and because research ethics requires prevention of unacceptable clinical harm to research subjects, including women and fetuses.

# 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 health care as well as access to family planning. These decisions should be informed by the physician's evidence-based judgment about the risk of teratogenicity. This information should include an evidence-based clinical judgment about whether teratogenic risk is clinically unacceptable and whether women of childbearing age should be excluded.
- 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.
- 3. When teratogenic risk is reliably judged to be clinically unacceptable, it is ethically impermissible to conduct the trial, because the risk/benefit ratio is unacceptable.
- 4. When teratogenic risk is reliably judged to be acceptable and when the woman has access to and utilizes effective prevention of pregnancy and has access to safe and effective termination of pregnancy, the clinical trial is ethically permissible. The woman should be informed that her enrollment is conditional on her undertaking measures to prevent pregnancy and that the study includes monitoring of these efforts, e.g. periodic pregnancy testing. Study design should include a plan to identify and responsibly manage the psychosocial impact of this requirement. The woman should also be informed that if a congenital abnormality is diagnosed, she will need to make a decision about the continuation of her pregnancy. It is ethically impermissible for the study design to recommend or require termination of pregnancy in these circumstances.
- 5. When the teratogenic risk is theoretical, the clinical trial is ethically permissible and the study design should explain why the above provisions are included or omitted.
- 6. Consent to participate must always be the autonomous, informed choice of the woman. Others may participate in her decision making only with her consent.

7. 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.

#### London, July 2018 revision of 2008 version

#### Citation for 2008 version:

Milliez J. FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Just inclusion of women of reproductive age in research. *Int J Gynecol Obstet* 2009;107:168. doi: 10.1016/j.ijgo.2009.07.006. PMID: 19664768.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 065: Inclusion of women of reproductive age in research. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 179–181.

# Guideline 066: Embryo Research

- 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).
- Embryo research is necessary to further improve fertility treatment.
   Laboratory evidence holds promise to elucidate the usefulness of stem cell

technology for the improved clinical management of disability, disease, and injury, including the improvement of fertility treatment.

- 4. In a pluralistic society, some object to research with embryos, some do not, and some support such research on religious or other moral grounds.
- 5. When embryos are created de novo, obtaining oocytes entails clinical risks for the woman.
- 6. 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 postmenarchal women. The ethical implications of providing oocytes from these sources are complex and controversial.
- 7. In a pluralistic society those who object to biomedical research using embryos on religious or other moral grounds must recognize that there are others in society who do not have such objections and may, indeed, regard such research to be ethically justified.
- 8. Scientific research using embryos must have prior approval by the oversight group authorized by applicable law.
- 9. Informed consent must be obtained for the use of gametes or embryos in research.
- 10. The creation of preimplantation embryos specifically for the purpose of research, and research on such embryos, is appropriate when the information cannot be obtained by research on existing supernumerary embryos.

- 1. In a pluralistic society, objection to SCNT research by some, on religious or other moral grounds, should not be considered a decisive factor in the ethical permissibility of SCNT research.
- 2. When gametes are collected, specific consent for the possibility of research on the creation or use of embryos must be sought.
- 3. In IVF programs, recipients of resulting embryos should be asked for consent to the use of their supernumerary embryos for research.
- 4. Embryos should not be created for purposes of research unless there is a demonstrable need for the planned studies, which must be submitted to research ethics committee appraisal and peer review, when research is either publicly or privately funded.
- 5. Women must be protected from coercion or undue inducement to donate oocytes, especially when they are vulnerable medically, psychologically, or socioeconomically.

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

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Embryo research. *Int J Gynecol Obstet* 2006;93:182–183. doi: 10.1016/j.ijgo.2006.03.008.

## Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 066: Embryo research. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 181–183.

# Guideline 067: Cytoplasmic Animal-Human Hybrid Embryos

- Stem cell research with embryos created by somatic cell nuclear transfer (SCNT) is an important tool for investigating disease behavior 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.
- 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

- Professionally responsible 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 or nonanimal uterus.
- 3. Somatic cell donors' autonomy should be respected by informed and voluntary consent based on adequate information. The consent process and form should clarify ownership claims, or lack of such claims, on results of research, including cell lines.
- 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, especially the fact that embryos may be created to isolate stem cells that may outlive the donors.

# London, July 2018 revision of 2008 version

# Citation for 2008 version:

Milliez J; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines concerning cytoplasmic animal–human hybrid embryos: FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. *Int J Gynecol Obstet* 2009;107:167. doi: 10.1016/j.ijgo.2009.07.007. PMID: 19664770.

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# **Guideline 068: Human Cloning**

# Background

- 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 clinically unsafe.
- 3. SCNT research has the potential to improve the effectiveness of patient care for disability, disease, and injury.
- 4. It is inconsistent with professionally responsible patient care for an obstetrician-gynecologist to offer, recommend, or provide clinical management that is known to be unsafe and for which clinical benefits remain theoretical.
- 5. In a pluralistic society those who object to some forms of biomedical research on religious or other moral grounds must recognize that there are others in society who do not have such objections and may, indeed, regard these forms of research to be ethically justified.

- Public education about the differences between reproductive cloning (making a biological copy of an individual) and therapeutic cloning (creating cell lines and perhaps organs for clinical care) is essential.
- 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 for human benefit.
- 3. In a pluralistic society, objection to SCNT research by some, on religious or other moral grounds, should not be considered a decisive factor in the ethical permissibility of SCNT research.
- 4. Research on human embryo stem cells, produced by SCNT, to produce various cell lines for therapeutic purposes, is ethically permissible, with the goal of improving patient care, subject to appropriate ethical guidelines.

#### London, July 2017 revision of 1997 version

#### Citation for 1997 version:

Report of the Committee for the Study of Ethical Aspects of Human Reproduction. Some ethical issues in the doctor/patient relationship. Patenting of human genes. Ethical aspects in the management of newborn infants at the threshold of viability. The ethical aspects of sexual and reproductive rights. Cloning in human reproduction. *Int J Gynecol Obstet* 1997;52:165–168. PMID: 9431887.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 068: Human cloning. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology.* London: FIGO; 2021: 185–186.

# **Guideline 069: Altering Genes in Humans**

## Background

- 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 profession 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 recognize 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."

#### Recommendations

1. 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 nontherapeutic genetic alteration (genetic enhancement).

- 2. Genetic alteration of somatic cells to treat or prevent 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. Somatic cell gene alteration in the fetus in utero should be undertaken only as approved research.
- Germ line genetic alteration is currently considered ethically controversial. It should be undertaken in humans only as approved research and only after approved research on nonhuman models supports efficacy and safety.
- 4. Nontherapeutic genetic alteration (genetic enhancement) is ethically controversial. It should be undertaken in humans only as approved research and only after approved research on nonhuman models supports efficacy and safety.
- 5. 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.

## London, July 2016 revision of 1997 version

## Citation for 1997 version:

Schenker JG. Report of the FIGO Committee for the Study of Ethical Aspects of Human Reproduction. International Federation of Gynecology and Obstetrics. *Int J Gynecol Obstet*. 1997;57:95–99. doi: 10.1016/s0020-7292(97)85615-9.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 069: Altering genes in humans. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 186–188.

# Guideline 070: Assessing Ethical and Peer Review Standards of Medical Journals

- 1. There is a strict professional responsibility to distinguish between reputable medical journals and unethically exploitive medical journals, to assure use of the highest level of evidence and avoid harm to patients and research from unreliable information.
- 2. 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.
- 3. A barrier to medical libraries', practitioners', and students' access to journals may be costs of subscription related to production, printing, and mailing expenses.
- 4. 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.
- 5. 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. Reputable journals sometimes provide "open access" to some papers.

- 6. 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.[1]
- 7. Such journals may lure conscientious but 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 plagiarized 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.
- 8. Characteristics of such journals are becoming more clear. Methods to attract submissions include approaching authors published in reputable journals and inviting submissions by email targeted to their area of research. They promise competent peer review, which is frequently minimal or nonexistent, 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.
- 9. 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 skillfully mirror websites of prominent mainstream journals.
- 10. Fraudulent journals, which now number in their hundreds, allow researchers and practitioners, many acting in good faith, to grow their curricula vitarum, 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. Nonexperts 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 health care, they may cause harm to patients by treatment based on scientifically flawed or unscientific data.

- 1. Those considering submissions to journals with which they are unfamiliar and/or accepting invitations to join their editorial boards, have the professional responsibility to research the journals' origins and credibility, and check them, for instance through Beall's list.[1]
- 2. Faculty mentors and promotion committees should make clear that publications in predatory journals should not be considered by any faculty member to be scholarly publications required for promotion.
- 3. 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.
- 4. 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.
- 5. 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 peer-reviewed journals.
- 6. Authors should be cautious in citing others' publications in their references, confining themselves only to research in journals published by medical and related associations or reputable medical or wider health institutions and publishing houses.
- 7. FIGO member societies 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.

#### Reference

[1] Beall J. Beall's list of potential predatory journals and publishers [archived]. https://beallslist.net/. Accessed June 21, 2021.

## London, July 2019 revision of 2015 version

## Citation for 2015 version:

Dickens B; FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Assessing ethical and peer review standards of medical journals. *Int J Gynecol Obstet* 2016;133:249–250. doi: 10.1016/j.ijgo.2016.02.003. PMID: 26972183.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 070: Assessing ethical and peer review standards of medical journals. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 188–191.

# **IX. Medical Education**

# Guideline 071: Gifts to Obstetrician-Gynecologists and Trainees

- 1. There is a long-standing practice of pharmaceutical companies and device manufacturers providing funds for medical education and also gifts to obstetrician-gynecologists and trainees, either in conjunction with medical education or in conjunction with promotional visits by industry representatives. These gifts include items of small value such as pens but range upward to free meals at very expensive restaurants in exchange for listening to an industry-prepared presentation by a "thought leader" in obstetrics and gynecology.
- 2. For many decades, the potential for this practice to bias clinical judgment and practice, although profound, was not appreciated. There is now ample evidence that industry support, and especially gifts, do bias clinical judgment and practice in obstetrics and gynecology and other specialties.
- 3. The obstetrician-gynecologist has the professional responsibility to protect the intellectual integrity of clinical judgment and practice from bias.
- 4. Support for medical education from industry is consistent with this professional responsibility, provided that obstetrician-gynecologists and healthcare organizations take effective measures to eliminate this source of bias.

## Recommendations

- Gifts from industry are not essential to education of obstetriciangynecologists and trainees. Individual obstetrician-gynecologists and healthcare organizations should adopt the ethical policy of refusing all gifts.
- 2. Obstetrician-gynecologists and healthcare organizations may accept funds from industry for medical education but only when the obstetriciangynecologist or healthcare organization retains autonomy and therefore control over the content, speakers, format, and evaluation of the educational program. These are known as unrestricted educational grants from industry.
- 3. Display booths at professional meetings should be in a space separate from that for educational activities. Gifts should not be permitted.

#### London, July 2017 revision of 2005 version

#### Citation for 2005 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical issues in medical education: gifts and obligations. *Int J Gynecol Obstet*. 2006;93:189–190. doi: 10.1016/j.ijgo.2006.03.010.

#### Citation for 2017 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 071: Gifts to obstetrician-gynecologists and trainees. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 192–193.

# Guideline 072: In Training

#### Background

 The primary commitment of the obstetrician-gynecologist is to serve women's reproductive health and well-being. Trainees who find themselves unable to deliver care to their patients for reasons of their personal conscience still have professional responsibilities to their patients. When trainees consider themselves for good reason to be obliged to place their personal conscientious commitments before the fulfillment of professional responsibility, they have a conflict of commitment. Because patients seek care from professionals and not private individuals, the burden of justification is on the trainee who believes that personal commitments should take precedence over professional responsibility in patient care.

- 2. It is unethical for a trainee not to fulfill the professional responsibility to inform all patients of all medically reasonable alternatives for their care in an evidence-based and unbiased fashion, including alternatives that an obstetrician-gynecologist is unwilling as a matter of conscience to provide. It follows that all trainees must master the fund of knowledge required to fulfill this professional responsibility.
- All trainees have the professional responsibility to see to it that every patient receives the clinical care she has authorized in the informed consent process. When a trainee has a conscience-based objection to providing a medically reasonable alternative, the trainee should refer the patient to a faculty member who does not have such an objection.
- 4. When in an emergency, patients' lives or their physical or mental health can be preserved only by procedures to which a trainee might otherwise object in conscience, the trainee has the professional responsibility to initiate emergency management and continue it until others without such objection can take over management of the patient.
- 5. Claims of conscientious objection by trainees must be documented and include evidence that the values and beliefs invoked as a matter of conscience are reasonably considered by faculty to values and beliefs of conscience.
- 6. Training programs should have a clear and comprehensive policy to guide trainees and faculty in matters of conscientious objection by a trainee. This policy should state that it is the expectation of the training program that graduates will not perform procedures to which a trainee has expressed conscientious objection, a measure intended to prevent dishonest assertions of conscientious objection.

# Recommendations

1. Educational programs should develop, implement, and enforce clear and comprehensive policies that define conscientious objection as a conflict of commitment, how and when assertions of conscientious objection should be documented, and a process for evaluating the acceptability of such assertions of conscience.

- 2. Assertions of conscientious objection do not include failure to master the fund of knowledge about objectionable procedures and their clinical sequelae.
- 3. Assertions of conscientious objection do not include failure to master the fund of knowledge and clinical skills to provide professionally responsible clinical management of objectionable procedures.
- 4. Assertions of conscientious objection apply only to participation in objectionable nonemergency procedures and not to learning about them.

#### London, July 2019 revision of 2006 version

#### Citation for 2006 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical guidelines on conscientious objection. *Int J Gynecol Obstet* 2006;92:333–334. doi: 10.1016/j.ijgo.2005.12.020. PMID: 16458897

#### Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 072: Conscientious objection in training. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 193–195.

# X. Women's Health Policy

# Guideline 073: The Obstetrician-Gynecologist as an Advocate for Women's Health

- 1. Obstetrician-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 a professional that women approach with health problems in this area. They therefore have a duty to provide care based on this professional knowledge and experience. The professional 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 inequitable exposure to violence, poverty, malnutrition, and displacement, and by denied opportunities for education or employment especially when they are unaware. This obligates the obstetrician-gynecologist to advocate improvement of the social status of women.

## Recommendations

- 1. Obstetrician-gynecologists are obliged individually and as a profession to monitor and publicize indices of reproductive health and provide data to sensitize 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 and prevention of exploitation.
- 2. 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 obstetrician/gynecologist.
- 3. Obstetrician-gynecologists should inform their 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 organizations, legislators, educators, lawyers, social scientists, and theologians. In addition, obstetrician-gynecologists are obligated to organize themselves and other professional and advocacy groups to ensure that essential health services are available for disadvantaged and underprivileged women.

## London, July 2016 revision of 1999 version

#### Citation for 1999 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. International Federation of Gynecology and Obstetrics. *Int J Gynecol Obstet*. 1999;66:301–303.

#### Citation for 2016 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 073: The obstetrician-gynecologist as an advocate for women's health. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 196–197.

# Guideline 074: Health Consequences of Child or Adolescent Marriage

- 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 a prevalent form of sexual abuse and exploitation [1].
- 2. The harmful psychosocial consequences are several, 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 United Nations Convention on the Rights of the Child "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 Guideline 052: Public health and policy dimensions of violence against women and Guideline 053: Clinical dimensions of violence against women.
- 5. In some cases marriage will not be immediately consummated, but in cases where it is, this may fall within the applicable legal definition of rape.
- 6. Medically, the risks of teenage pregnancy are well documented. See Guideline 031: Adolescent pregnancies. 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. Girls may not be immediately forthcoming about violence they have experienced. Obstetrician-gynecologists, midwives, and other

healthcare professionals may be the first clinicians these adolescent women encounter in the professional relationship protected by confidentiality and thus in the absence of, for instance, husbands or mothers-in-law. Healthcare professionals may encounter more girl-bride victims of violence than they realize, and should have a low threshold for enquiring about this possibility. See Guideline 052: Public health and policy dimensions of violence against women and Guideline 053: Clinical dimensions of violence against women.

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

- Member societies of FIGO should advocate with governments, societies, and families against child marriage and for the continued education of all girls. This includes providing education and helping to create awareness of the biopsychosocial complications of early pregnancy.
- Member societies of FIGO should support the basic and continuing education of all relevant healthcare professionals, including obstetriciangynecologists, 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 Guideline 052: Public health and policy dimensions of violence against women and Guideline 053: Clinical dimensions of violence against women.
- 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 counseled on the advantages of postponing pregnancy and be supported in acquiring contraception. Involvement of male partners should similarly be encouraged.
- 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 protected by the professional obligation of confidentiality, in a youth-friendly environment.
- 6. Healthcare professionals should be trained in diagnosing, documenting, and caring for girls exposed to violence. See Guideline 052: Public health and

policy dimensions of violence against women and Guideline 053: Clinical dimensions of violence against women.

- 7. When laws forbidding girl marriage are not respected, it is everyone's ethical obligation to highlight this fact without stigmatizing or penalizing the girls.
- 8. Professional societies should advocate governments to implement the United Nations Convention on the Rights of the Child [2] where it has not been implemented.

## References

[1] UNFPA. Marrying too young: end child marriage. New York: UNFPA; 2012. https://www.unfpa.org/sites/default/files/pub-pdf/MarryingTooYoung.pdf. Accessed July 3, 2019.

[2] United Nations. The United Nations Convention on the Rights of the Child. September 2, 1990. https://www.ohchr.org/en/professionalinterest/pages/crc.aspx. Accessed July 3, 2019.

## London, July 2019 revision of 2014 version

#### Citation for 2014 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Ethical considerations on the health consequences of child or adolescent marriage. *Int J Gynecol Obstet* 2015;128:83–84. doi: 10.1016/j.ijgo.2014.10.002. PMID: 25458407.

## Citation for 2019 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 074: Health consequences of child or adolescent marriage. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 198–200.

# Guideline 075: Professionally Responsible Advocacy for Professional Liability Law

# Background

1. Professional liability with incurred expenses for premiums, attorney fees, payouts, and other costs has become of increasing concern for obstetrician-gynecologists around the world. Perhaps of even greater concern is public

vilification of physicians and criminalization of negligence. These changes are not only a source of personal stress but also contribute to obstetriciangynecologists leaving practice.

- 2. The ethical framework is based on the rights of patients and the responsibilities of obstetrician-gynecologists. Patients have the right to clinical management that meets a professional standard of care. Obstetrician-gynecologists have the professional responsibility to provide such care. (See Guideline 001: Professionalism in obstetric and gynecologic practice). Expert witnesses have the professional responsibility to demonstrate that their opinions meet an accepted professional standard of care.
- 3. Healthcare organizations and the state share in the professional responsibility to provide patient care that meets an accepted professional standard. To fulfill this shared responsibility, healthcare organizations should work with physicians to ensure that organizational resources required by professional standards are routinely available. When such resources are not available, there is no justified claim against physicians for failing to meet a higher standard of care.
- 4. Healthcare organizations and the state should support physicians in creating and sustaining clinically meaningful systems of accountability. The societal right to accountability is limited. In particular, there is no societal right to accountability based on extraneous matters such as excessive documentation for purposes of defensive medicine. Obstetrician-gynecologists should advocate for policies that require healthcare organizations and the state to create and sustain clinically meaningful accountability for patient care.
- 5. The right to provision of patient care that meets an acceptable professional standard also means that professional liability law should require and be limited to evaluation of patient care against such a standard. This approach to professional liability reinforces and therefore does not conflict with the professional commitment to such care. Public vilification of physicians and criminalization of negligence, except in extreme cases, threaten this commitment, by incentivizing physicians to put their self-interest first rather than the interests of patients.

## Recommendations

1. FIGO members in each country should undertake an analysis of the extent to which professional liability law is based on providing patient care that meets an acceptable professional standard. FIGO members in each country should

then advocate for changes in professional liability guided by the following considerations:

- i. All obstetrician-gynecologists and healthcare organizations have professional responsibility for the provision of patient care that meets an accepted professional standard.
- ii. Negligence is defined as the failure to adhere to a professional standard of care resulting in injury to a patient or similarly affected party. An adverse outcome is not by itself evidence of negligence.
- iii. Even excellent patient care will sometimes result in non-negligent adverse outcomes.
- 2. Patients or other affected parties have the right to initiate civil actions against physicians or other responsible parties for alleged negligence.
- 3. Professional liability law should hold physicians and/or other responsible parties accountable for adherence to an accepted professional standard of patient care.
- 4. Professional liability law should require expert witnesses to demonstrate that their opinions meet an accepted professional standard of care and prohibit testimony that does not do so.
- 5. Judicial processes should be fair to all parties and efficient, to protect the rights and interests of all parties and to use social resources responsibly.
- 6. FIGO categorically opposes public vilification of physicians and criminalization for alleged negligence except in extreme circumstances, because they are counter-productive in that they do not promote patient safety and quality but threaten to undermine professionalism in patient care.

# London, July 2016 (new)

## Citation for 2016 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Professionally responsible advocacy for professional liability law. *Int J Gynecol Obstet* 2017;136:247–248. doi: 10.1002/ijgo.12026. PMID: 28099743.

## Citation for 2020 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 075: Professionally responsible advocacy for professional liability law. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 200–202.

# Guideline 076: Criminal Proceedings for Medical Errors in Obstetrics and Gynecology

- 1. "Criminalization of medical errors" refers here not only to formal criminal charges laid by government authorities but also to threats to bring criminal charges made by individuals or government authorities.
- 2. While exceedingly rare, there has been a perceived increase in criminalization of medical errors in many countries.
- 3. A crime is an act, or omission to fulfil a duty to act, that causes harm not only to another but that also harms or gravely offends the wider community, justifying punishment of the offender rather than simply compensation to an injured individual.
- 4. Criminalization requires two conditions to be met: (a) a harmful act or omission constituting a gross deviation from a legally required standard of care, often displayed in a pattern of conduct; and (b) a culpable state of mind, showing that the harmful act or omission was undertaken purposely to cause harm, knowing that it might cause harm, or recklessly regarding whether it would risk causing harm.
- 5. Adverse outcomes occur not uncommonly in obstetrics and gynecology, despite focused and sustained adherence to processes to ensure patient safety and quality of care. An adverse outcome, no matter how severe, does not in itself justify the conclusion that negligence has occurred, because the vast majority of adverse outcomes do not result from deviations from a standard of care, but from current scientific and clinical limitations of obstetric and gynecologic practice. The burden of proof therefore is on the individual or governmental authority that claims that an alleged medical error should be liable to punishment under criminal law.
- 6. Unjustified criminalization of medical errors, such as through charges of manslaughter, criminal negligence causing death or serious bodily harm, or assault, causes disproportionate harm to obstetrician-gynecologists' reputations and self-confidence, and to patients and societies dependent on access to their professional services.
- 7. The obstetrician-gynecologist has the professional responsibility to adhere to processes designed to ensure patient safety and quality of care.

- 8. Leaders in obstetrics and gynecology have the professional responsibility to create an organizational culture of professionalism that provides oversight of processes of patient safety and quality of care.
- 9. The ethical principle of justice precludes criminal proceedings or threats of criminal proceedings when there is no prima facie evidence that the criteria for a crime have been met.
- 10. The ethical principle of justice precludes issue of an arrest warrant, arrest itself, or confiscation of travel documents, when there is no prima facie evidence that the criteria for a crime have been met.

- 1. Obstetrician-gynecologists and leaders in the specialty should observe the well-recognized, internationally accepted professional responsibility to enhance patient safety and quality of care, in order to minimize medical errors.
- 2. Obstetrician-gynecologists and their professional associations should advocate for reform of criminal law to prevent prosecutorial abuses when adverse outcomes occur.
- 3. To achieve this reform, obstetrician-gynecologists and their professional associations should advocate for the creation of mandatory pretrial review of criminal charges alleging medical error, conducted by government-supported independent peer review committees, whose reports would be available to parties in related criminal proceedings. This pretrial review must involve the obstetrician-gynecologist concerned.
- 4. Obstetrician-gynecologists and their professional associations should advocate for the legal prohibition of issue of an arrest warrant, arrest itself, confiscation of travel documents, or other measures when there is no prima facie evidence that the criteria for an alleged crime have been met.
- 5. Obstetrician-gynecologists and their professional associations should support obstetrician-gynecologists to bring civil proceedings, such as for malicious prosecution or defamation, against individuals or governmental authorities that bring or threaten to bring charges when they are groundless, i.e. there is no prima facie evidence that the criteria for an alleged crime have been met. Because of the serious consequences for the individual obstetriciangynecologist and the medical profession, timely and fair compensation should be awarded.

#### London, July 2017 (new)

#### Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 076: Criminal proceedings for medical errors in obstetrics and gynecology. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 203–205.

# **Guideline 077: Human Genes and Patenting**

- Governments introduce patenting systems in order to encourage investment in industrial and related innovation, and to protect discoveries from commercial competition by awarding time-specific monopolies, for instance for 20 years in the United States, on exploitation of their discoveries provided that innovators make their discoveries obvious and readily accessible, that is, "patent," to the world.
- 2. Patents are a form of intellectual property (IP), available only for discoveries that are new, useful, and products of human creation and industry, not products of nature. Knowledge of human gene sequences may be new and of immense potential in the treatment and/or prevention of diseases, but leading courts have ruled that, in law, gene sequences are products of nature, and so not themselves patentable.
- 3. Patents are either product patents or process patents. A product patent, such as for a drug, protects the holder against competition from another possessing the same product, even if developed by a different means. A process patent provides a monopoly on a particular creative process, for instance to identify a gene sequence, but not on what the process produces. Anyone may produce the same product by a different process, such as by improving an original means.
- 4. Countries differ on whether they grant product or process patents, and on how far they recognize patents granted in other countries, although there are moves toward internationalization and harmony among countries.

- 5. Monopolies on exploitation of patent rights for commercial gain can govern but restrict access to greatly beneficial knowledge. It is known, however, for a university, funded for instance by public taxes or charities, to acquire a patent in order to promote free access to its product or process, and exclude any commercial agency such as a profit-seeking corporation from holding the patent and disallowing use except for payment. Payments are called "royalties" because historically patents were royal grants.
- 6. A concern is that commercial investors in costly acquisition of patents, for instance for gene products or probes, will seek returns by aggressive marketing, leading to premature use, overuse, or unsuitable use, contrary to patients' well-being.
- 7. IP law can be complex, nationally and internationally, and expensive to litigate depending on technologies involved in acquisition and protection of valuable patents. Decisions on award of patents are made in countries' patent offices that employ scientists, engineers, and related technicians. Patent offices are not necessarily structured to address broader social, health, economic, or ethical implications of their decisions.

- Governments, the international community, and health professional organizations have responsibilities to address the implications of granting and/or refusing to grant product or process patents regarding human genes, in order to protect the public interest. Health professional organizations should accordingly offer and be willing to work with patent offices in evaluation of patent applications.
- 2. Health professional organizations, in collaborating with patent offices and/ or government departments, and in public education and advocacy, should situate the impact of patenting decisions affecting genetic medicine in the context of broader social and international interests, including advancement of global health equity.
- 3. Health practitioners and their professional organizations should be willing to collaborate with public-sector and/or private-sector advocates and litigants in promotion, protection, or refusal of patents, when the profession considers the advocacy and/or litigation will advance patients' access to the benefits of genetic health and medicine.

#### London, July 2018 revision of 1997 version

#### Citation for 1997 version:

Report of the Committee for the Study of Ethical Aspects of Human Reproduction. Some ethical issues in the doctor/patient relationship. Patenting of human genes. Ethical aspects in the management of newborn infants at the threshold of viability. The ethical aspects of sexual and reproductive rights. Cloning in human reproduction. *Int J Gynecol Obstet* 1997;52:165–168. PMID: 9431887.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 077: Human genes and patenting. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 205–207.

# **Guideline 078: Violence Against Healthcare Professionals**

- In many countries, healthcare professionals, including obstetriciangynecologists, have been subjected to violence, including murder. In some countries, physicians who provide termination of pregnancy under the provisions of applicable law have been assaulted and killed. These physicians have not broken any law. Such assault and killing are criminal acts.
- 2. In some countries, during times of military conflict, physicians have been tortured and killed merely because they cared for injured patients who were regarded as the enemy or family members of the enemy. It is well accepted in military medical ethics that the uniform or national or other affiliation is irrelevant; clinical management should be based on triage, a clinical and not political concept. In addition, healthcare facilities have been directly targeted by ground and air attack by insurgents, terrorists, and governments, resulting in injuries and death to healthcare professionals and patients. It is well understood in military ethics that healthcare facilities are not to be targeted for direct attack. There is also a very high burden of proof in just war theory for attacks on nearby targets that might also damage or destroy healthcare facilities, especially those caring for the wounded and injured, laboring women, and children. Direct attacks on healthcare facilities should

be considered crimes against humanity. Finally, nongovernmental healthcare organizations, to fulfill their clinical mission, must position personnel near or in conflict zones. Leadership should not do so recklessly, i.e. when the risk of injury or death to healthcare professionals cannot be responsibly minimized.

# Recommendations

- 1. Obstetrician-gynecologists and their member societies have the professional responsibility to advocate for the impartial application of criminal law to perpetrators of criminal violence against healthcare professionals with especially vigorous advocacy in the case of lethal criminal violence.
- 2. Obstetrician-gynecologists and their member societies have the professional responsibility to advocate for the prevention of criminal violence against healthcare professionals, especially when current criminal law is not an adequate deterrent.
- 3. Obstetrician-gynecologists and their member societies have the professional responsibility to advocate against capture, abuse, and torture of healthcare professionals who have done nothing more than discharge their professional responsibilities to their patients, including those who are wounded or sick combatants.
- 4. Obstetrician-gynecologists and their member societies have the professional responsibility to advocate for the prosecution of crimes against humanity in direct or unjustified indirect attacks on healthcare facilities in appropriate national and international courts.
- 5. Obstetrician-gynecologists and their member societies have the professional responsibility to advocate that leadership of nongovernmental healthcare organizations make prudent decisions about the insertion into and extraction of healthcare professionals from conflict zones.
- 6. Leaders of healthcare facilities should resist efforts to use their facility as military depots or garrisons, consistent with their responsibility for the safety of their patients and colleagues.

# London, July 2018 (new)

# Citation:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 078: Violence against healthcare professionals. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 207–208.
# Guideline 079: Brain Drain of Healthcare Professionals

#### Background

- The worldwide shortage of healthcare professionals, coupled with a disproportionate concentration of health professionals in high-income nations and urban areas, and brain drain of health workforce from lowincome countries prevent the achievement of reduced child and maternal mortality, increasing vaccine coverage, and battling epidemics such as HIV/ AIDS in low-income countries.
- 2. Africa bears 24% of the global burden of disease but has only 3% of the health workforce. High-income countries have only one-third of the world's population; they contain three-fourths of the 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 healthcare professionals, aggravated by brain drain of health workforce from Africa, Asia, and Pacific countries to high-income countries, contribute to increased maternal, fetal, and neonatal mortality and morbidity at vastly different rates in high-income and low-income countries.
- 4. About 35% of pregnant women in low-income countries have no access to or contact with health personnel before delivery. Only 57% give birth with a skilled attendant present. Rural and poor women often have no access to maternal health services or cannot afford it. Thirty-six countries in sub-Saharan Africa have severe shortages of healthcare professionals.
- 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% of all maternal deaths occur in middle- and low-income countries, with some 84% concentrated in sub-Saharan Africa and South Asia where brain drain hits most.
- 6. Evidence shows that millions of lives could be saved each year with proven, cost-effective interventions that require the availability, training, and retaining of adequate numbers of healthcare professionals.
- 7. At least 2.3 trained healthcare professionals are needed per 1000 people to reach 80% of the population with skilled attendance at birth and child immunization. It will take an additional 2.4 million physicians, nurses, and

midwives to meet the needs, along with an additional 1.9 million pharmacists, health aides, technicians, and other auxiliary personnel. However, most of the demand is concentrated in high-income countries due to an increasing aging population and increasing demand for high-tech care.

8. Low-income nations spend many millions of dollars each year to educate healthcare professionals who leave their home countries to work in North America, Western Europe, and South Asia.

#### Recommendations

- 1. FIGO supports the approach of the World Health Organization, which has advocated for a comprehensive, four-pillar approach including: improvement of data on healthcare professionals' migration, development of innovative policy responses, evaluation of the effectiveness of international interventions, and international advocacy for workforce issues.
- 2. Brain drain of the health workforce from low-income to high-income countries should be regulated. It deprives source countries from the scarcest human resources, undermines health service, and markedly widens healthcare discrepancies between high-income and lower-income countries.
- Temporary return of qualified health professionals, and their virtual participation through conferences, telecommunication, and internet should be encouraged as it contributes to improvement of health care in the country of origin.
- 4. High-income countries that are recipients of health professionals should develop a mechanism of assistance and transfer of healthcare technology to low-income countries from which they receive a large number of health professionals.
- 5. Recipient countries should ensure availability of suitable jobs in their health system before issuing immigrant visa to health professionals from other countries.
- 6. High-income countries should invest in medical education and training of health professionals in lower-income countries to overcome the insufficient overall investment that exists.
- 7. In some countries where the underproduction of healthcare professionals is a major problem, task-shifting and the assembly of new cadres of professionals should be encouraged, such as physician assistants, nurses, and pharmacy assistants.

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

#### London, July 2018 revision of 2009 version

#### Citation for 2009 version:

FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health. Brain drain of healthcare workers. *Int J Gynecol Obstet* 2010;108:174–175. doi: 10.1016/j.ijgo.2009.10.001. PMID: 19932652.

#### Citation for 2018 revision:

FIGO Committee on Ethical and Professional Aspects of Human Reproduction and Women's Health. Guideline 079: Brain drain of healthcare professionals. In: Chervenak FA, McCullough LB, eds. *FIGO Ethics and Professionalism Guidelines for Obstetrics and Gynecology*. London: FIGO; 2021: 209–211.

# XI. Concordance of 2015 Edition with 2020 Edition

# A. General issues in women's health and advocacy

A1. The role of the obstetrician-gynecologist as an advocate for women's health 1999 – Guideline 073: The obstetrician-gynecologist as an advocate for women's health.

A2. Violence against women 2007 – Guideline 052: Public health and policy dimensions of violence against women.

A3. Ethical issues after sexual assault 2014 – Guideline 050: Caring for patients after sexual assault.

A4. Ethical guidance on healthcare professionals' responses to violence against women 2014 – Guideline 053: Clinical dimensions of violence against women.

A5. Sex selection for nonmedical purposes 2005 – Guideline 017: Sex selection for nonmedical purposes.

A6. Ethical framework for gynecologic and obstetrical care 2007 – Guideline 001: Professionalism in obstetric and gynecologic practice.

A7. Guidelines regarding informed consent 2007 – Guideline 004: Informed consent.

A8. The ethical aspects of sexual and reproductive rights 1997 – Guideline 016: Sexual and reproductive rights.

A9. Some ethical issues in the doctor–patient relationship 1997 – Guideline 002: Maintaining boundaries in the professional relationship with patients.

A10. Ethical issues in treating family members and close friends 2015 – Guideline 009: Treating family members and close friends.

A11. Ethical guidelines in regard to terminally ill women 1999 – Guideline 060: Care of terminally ill patients.

A12. Confidentiality, privacy, and security of patients' health care information 2005 – Guideline 005: Confidentiality.

A13. Female genital cutting 2006 - Guideline 054: Female genital cutting.

A14. Ethical guidelines on conscientious objection 2005 – Guideline 014: Conscientious objection.

A15. Professional obligation to fellow obstetricians and gynecologists 2006 – Guideline 001: Professionalism in obstetric and gynecologic practice.

A16. Harmful stereotyping of women in health care 2011 – Guideline 015: Harmful stereotyping of women in health care.

A17. Adolescent youth and reproductive health care and confidentiality 2008 – Guideline 006: Confidentiality and adolescent patients.

A18. HPV vaccination and screening to eliminate cervical cancer 2007 – Guideline 051: HPV vaccination and screening to prevent cervical cancer.

A19. Just inclusion of women of reproductive age in research 2008 – Guideline 065: Inclusion of women of reproductive age in research.

A20. Disclosing adverse outcomes in medical care 2010 – Guideline 007: Disclosing adverse outcomes of medical care.

A21. Ethical issues in the management of severely disabled women with gynecological problems 2011 – Guideline 049: Management of severely disabled women with gynecologic problems.

A22. Cross-border reproductive services 2012 – Guideline 026: Cross-border reproductive services.

A23. Brain drain of healthcare workers 2009 – Guideline 079: Brain drain of healthcare professionals.

A24. Ethical considerations on health consequences of child or adolescent marriage 2014 – Guideline 074: Health consequences of child or adolescent marriage.

A25. Ethical issues in women's post-reproductive lives 2014 – Guideline 056: Women's post-reproductive lives.

A26. Patients' refusal of recommended treatment 2014 – Guideline 008: Patients' refusal of recommended treatment.

A27. Ethical health care of sex workers 2015 – Guideline 057: Health care of sex workers.

# B. Issues in genetics and embryo research

B1. Human cloning 2005 – Guideline 068: Human cloning.

B2. Patenting human genes 1997 - Guideline 077: Human genes and patenting.

B3. Embryo research 2005 – Guideline 066: Embryo research.

B4. Ethical guidelines on the sale of gametes and embryos 1997 – Guideline 019: The sale of gametes and embryos.

B5. Ethical guidelines regarding altering genes in humans 1997 – Guideline 069: Altering genes in humans.

B6. Donation of genetic material for human reproduction 2007 – Guideline 018: Advocacy for evidence-based and ethically justified state regulation of advances in reproductive medicine.

B7. Guidelines for use of embryonic or fetal tissue for therapeutic clinical applications 2007 – Guideline 028: Clinical applications of embryonic or fetal tissue.

B8. Testing for genetic predisposition to adult-onset disease 2001 – Guideline058: Genetic and genomic testing for risk of adult-onset disease.

B9. Ethical guidelines concerning cytoplasmic animal-human hybrid embryos2008 - Guideline 067: Cytoplasmic animal-human hybrid embryos.

B10. Professional obligations related to developments in genomics and proteomics in human testing 2008 – Guideline 024: Genomics and proteomics.

# C. Issues in conception and reproduction

C1. Ethical guidelines on multiple pregnancy 2005 – Guideline 032: Multiple pregnancy.

C2. Ethical aspects of gamete donation from known donors 2000 – Guideline 020: Directed gamete donation.

C3. Surrogacy 2007 – Guideline 021: Surrogacy.

C4. Ethical issues concerning prenatal diagnosis of disease in the conceptus 1991 – Guideline 023: Prenatal diagnosis and screening.

C5. Ethical aspects of HIV infection and reproduction 1997 – Guideline 034: Pregnancy and HIV-positive patients.

C6. HIV and fertility treatment 2005 – Guideline 035: HIV and fertility treatment.

C7. Ethical considerations with oocyte and ovarian cryopreservation in women 2005 – Guideline 022: Oocyte and ovarian cryopreservation.

C8. Ethical guidelines on iatrogenic and self-induced infertility 2006 – Guideline 025: latrogenic and self-induced infertility.

C9. Fertility centers and whom they should treat 2008 – Guideline 027: Fertility centers and whom they should treat.

# D. Issues regarding pregnancy and maternal/fetal issues

D1. Brain death and pregnancy 2012 – Guideline 039: Brain death and continued pregnancy.

D2. Ethical aspects regarding cesarean delivery for nonmedical reasons 1998 – Guideline 037: Cesarean delivery for nonmedical reasons.

D3. Ethical guidelines regarding interventions for fetal well-being 2011 – Guideline 033: Intrapartum interventions for fetal well-being.

D4. Definition of pregnancy 1998 – Guideline 029: Definition of pregnancy.

D5. Ethical issues in the management of the severe congenital anomalies 2012 – Guideline 023: Prenatal diagnosis and screening.

D6. Ethical aspects concerning termination of pregnancy following prenatal diagnosis 2007 – Guideline 046: Termination of pregnancy following prenatal diagnosis.

D7. An encephaly and organ transplantation 2007 – Guideline 040: An encephaly and organ transplantation.

D8. Safe motherhood 2012 - Guideline 031: Safe motherhood.

D9. Ethical guidelines on obstetric fistula 2006 – Guideline 041: Obstetric fistula.

D10. Pregnancy and HIV-positive patients 2008 – Guideline 034: Pregnancy and HIV-positive patients.

D11. Planned home birth 2012 - Guideline 038: Planned home birth.

D12. Task-shifting in obstetric care 2012 – Discontinued.

D13. Ethical issues in adolescent pregnancies 2014 – Guideline 031: Adolescent pregnancies.

# E. Issues regarding neonates

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E2. Resuscitation of newborns 2006 - Guideline 063: Resuscitation of newborns.

E3. Ethical aspects in the management of malformed newborn infants 1997 – Guideline 064: Management of infants with severe anomalies.

E4. Ethical aspects concerning neonatal screening 2008 – Guideline 061: Neonatal screening.

# F. Issues in contraception and abortion

F1. Ethical considerations in sterilization 2000 – Guideline 045: Sterilization and Guideline 048: Ethical issues in the management of severely disabled women with gynecologic problems.

F2. Ethical considerations respecting the use of antiprogestins 1994 – Guideline 059: The use of anti-progestins.

F3. Ethical aspects of the introduction of sterilization methods for women 1997 – Guideline 042: Counseling women about contraceptive methods.

F4. Ethical aspects of induced abortion for nonmedical reasons 1998 – Guideline 047: Induced abortion for nonmedical reasons.

F5. Guidelines in emergency contraception 2002 – Guideline 043: Emergency contraception.

F6. Ethics in family planning 2008 - Guideline 044: Family planning.

# G. Issues in advertising and marketing health services

G1. Ethical background for advertising and marketing 2003 – Guideline 013: Advertising.

G2. Recommendations on conflict of interest, including relationships with industry 2014 – Guideline 011: Responsibly managing conflicts of interest in clinical practice and research.

G3. Ethical considerations regarding requests and offering of cosmetic genital surgery 2014 – Guideline 055: Cosmetic genital surgery.

G4. Recommendations for medical information and advertising on the web 2003 – Guideline 012: Helping patients access medical information on the world wide web.

# H. Ethical issues in medical education

H1. Ethical issues in medical education: gifts and obligations 2005 – Guideline 071: Gifts to obstetrician-gynecologists and trainees.

H2. Guidelines on ethical issues involved in the advertising of credentials and education 2003 – Guideline 013: Advertising.

H3. Ethical guidelines on conscientious objection in training 2014 – Guideline 072: Conscientious objection in training.

H4. Assessing ethical and peer review standards of medical journals 2015 – Guideline 070: Assessing ethical and peer review standards of medical journals.

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FIGO is a professional organization that brings together more than 130 obstetrical and gynecological associations from all over the world. FIGO's vision is that women of the world achieve the highest possible standards of physical, mental, reproductive, and sexual health and wellbeing throughout their lives. We lead on global programme activities, with a particular focus on sub-Saharan Africa and South East Asia.

FIGO advocates on a global stage, especially in relation to the Sustainable Development Goals (SDGs) pertaining to reproductive, maternal, newborn, child and adolescent health, and non-communicable diseases (SDG3). We also work to raise the status of women and enable their active participation to achieve their reproductive and sexual rights, including addressing female genital mutilation (FGM) and gender-based violence (SDG5).

We also provide education and training for our Member Societies and build capacities of those from low-resource countries through strengthening leadership, good practice, and promotion of policy dialogues.

FIGO is in official relations with the World Health Organization (WHO) and consultative status with the United Nations (UN).



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