FIGO Ethics And Professionalism Guideline 081: Responsibly Managing Clinical Variation To Improve Quality

Background

1. The concept of quality in healthcare 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 varies 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, organisational 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 organisational 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 work-up and management of pelvic pain, the chair authorises the group to implement the quality improvement measures that they have identified and report back the results of doing so. Governmental agencies, such as NICE in the United Kingdom, FIGO, and national associations of obstetricians and gynecologists have published evidence-based guidelines which can be used to responsibly minimise 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 obstetrician-gynecologist 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, post-operative infection.

5. There is ethical controversy about whether quality improvement is research, i.e., a clinical experiment designed to produce generalisable knowledge.

Recommendations

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. Organisational 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.

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

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.

About FIGO

FIGO is a professional organisation that brings together 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 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 a consultative status with the United Nations (UN).