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A Life-Course Perspective for Women's Health Care

Safe, Ethical, Value-Based Practice with a Focus on Prevention

CALVIN J. HOBEL • JOSEPH C. GAMBONE

CLINICAL KEYS FOR THIS CHAPTER

- Clinical practice in obstetrics and gynecology, based upon the principles of safe, ethical and value-based care, is facilitated by viewing wellness and sickness in the context of a **life-course perspective**. Effective clinical care of mother and child must begin early, even before conception, and continue throughout life.
- Adaptive developmental plasticity and epigenetic modification of genes during and after pregnancy can have a significant impact on chronic diseases later in life.
- Clinicians should incorporate the major ethical principles of nonmaleficence, beneficence, autonomy, and justice into their practices, along with the duties and ideals of confidentiality and multidisciplinary collaboration.
- Regulatory, economic, and public pressure make assessment and improvement of safety and value essential in the delivery of women's health care. Optimal health outcomes can only be achieved when principles from continuous quality assessment and high reliability organizations are combined with the systematic approach of safety science and evidence-based medicine.
- The promising area of clinical preventive services in obstetrics and gynecology, as in all health care, is transforming the practice of medicine in a very positive way.

This chapter of *Essentials of Obstetrics and Gynecology* is being revised at a time when the health and wellness of the population of the United States and some other developed countries of the world are being evaluated and questioned. A recent study by the Harvard Business School conducted by Professor Michael Porter and his team ranked the United States only 70th in the world in terms of overall health and wellness. **Despite the fact that the United States spends far more on health care** (nearly 18% of gross domestic product or GDP) **than any other nation, it continues to be ranked only about 37th out of 191 nations for health status and health system performance.** Further, the United States is ranked only 46th for average life-expectancy and 42nd for infant mortality by the World Health Organization (WHO). Clearly, the United States must strive to improve its standing on these and other measures of performance. This is especially important at a time when the health care delivery system enters the era of the Affordable Care Act (ACA), and efforts to provide care to all citizens at a reasonable cost are underway.

Obstetrics and gynecology is one of the most exciting and challenging areas of health care, with a

number of significant opportunities for improvement such as infant and maternal mortality. The specialty provides students and young physicians in training with the knowledge and skills necessary to improve the health of women and their children very early in their lives. In this first chapter of the book, some basic principles and guidelines for improving health care are provided, and several important factors that are influencing the health of women and their children are suggested.

Principles of Practice

There are four basic principles for practicing and improving health care. First, the safety of our patients must always be paramount. In recent years we have made major improvements in patient safety, in large part by emphasizing teamwork and implementing practices proven to be effective in the airline industry. **Second, we must be true to our personal pledge made when taking the Hippocratic Oath—to adhere to ethical practices.** **Third, we must transform to a value-based system of health care delivery.** Because medicine has become very complex, we must be open to a

more cost-effective multidisciplinary approach to both diagnostic and therapeutic practice. Performance improvement efforts, practice management skills, and effective communication are all necessary to efficiently optimize clinical outcomes and value. **Fourth**, and perhaps most importantly, **we must focus on the prevention and early mitigation of disease**, in addition to our continued focus on its treatment. This should occur in a patient-centered manner, meeting their needs and expectations.

For this reason, we emphasize an approach called a *life-course perspective for clinical practice*, beginning with preconception health, continuing throughout pregnancy, the postpartum period (interconception health), and then giving children and their mothers a **health perspective** for adopting and maintaining healthy living.

Before delving more deeply into these principles of practice (safety, ethics, value, and prevention), some newer concepts about the origins of disease are important to mention.

LIFE-COURSE PERSPECTIVE

When does disease begin and lead to pathology and illness during the course of life?

First, although genetics is beginning to provide a much better understanding of the etiology of poor health, it probably accounts for only about one-third of the direct causes. Imprinted genes from both the mother and the father play an important role in passing on characteristics to the offspring. This imprinting process maintains the phenotype of the family in subsequent generations. However, some imprinted and nonimprinted genes can be upregulated or downregulated by subsequent epigenetic modifications, due to environmental influences. For example, person X with gene A has a disease but person Y with the same gene does not. Clearly there is more to human development and disease risk than genetic makeup. Currently it is thought that factors such as poverty or abnormal health behaviors (poor nutrition and smoking) and/or environmental conditions can influence the expression of gene A without actually changing its genomic makeup. This may occur directly or these factors may activate another gene, A-2 downstream, which may then affect gene A. This process whereby human cells can have the same genomic makeup but different characteristics is referred to as **epigenetics (literally meaning “on top of genetics”)**, an exciting new frontier.

The developmental origins of adult disease hypothesis (Barker hypothesis) postulates that perturbations in the gestational environment may influence the development of adult diseases such as cardiovascular disease, obesity, diabetes, and stroke. Current evidence suggests that this occurs through the reprogramming of gene expression via epigenetic changes in chromatin structure. Epigenetic changes in chromatin

structure include altered DNA methylation by both histone acetylation and methylation.

Since the last edition of this text, investigators have determined that alterations in the in utero environment during pregnancy may result in modifications to the chromatin structure. These modifications may lead to persistent changes in postnatal gene expression which may render the child more susceptible to early onset adult disease. **The conditions during pregnancy that account for these epigenetic changes are preeclampsia, preterm birth, intrauterine growth restriction (IUGR), obesity, diabetes, poor nutrition, smoking, and some cancers.** Even the mothers with these pregnancy conditions are themselves at greater risk for cardiovascular disease, hypertension, and diabetes later in life. The onset for these conditions occurs earlier in life compared to those women who have normal pregnancies. Thus **having a normal pregnancy may be protective of disease later in life.**

It is now thought that the effect of harmful behaviors and our environment on the expression of our genes may account for up to 40% of all premature deaths in the United States. Two of the top behavioral factors related to this premature death rate are obesity (and its usual physical inactivity) and smoking. Environmental exposures to metals, solvents, pesticides, endocrine disruptors, and other reproductive toxicants are also major concerns.

Second, in human biology, a phenomenon called adaptive developmental plasticity plays a very important role in helping to adjust behavior to meet any environmental challenge. In order to understand human development over time (*a life-course perspective*), one must first understand what is normal and what adverse circumstances may challenge and then change normal development of the fetus. **These protective modifications of growth and development which are programmed in utero to prevent fetal death, may become permanent.** The price the fetus may pay for short-term survival is later vulnerability to conditions such as obesity, hypertension, insulin resistance, atherosclerosis, and even diabetes.

In relation to individual X and individual Y with the same genomic makeup but different in utero environmental influences, metabolic changes that may be initiated in utero in response to inadequate nutritional supplies ([Figure 1-1](#)) can lead to insulin resistance and eventually the development of type 2 diabetes. These adaptive changes can even result in a reduced number of nephrons in the kidneys as a stressed fetus conserves limited nutritional resources for more important organ systems in utero. This can then lead to a greater risk of hypertension later in life.

This series of initially protective but eventually harmful developmental changes was first described in humans by David Barker, a British epidemiologist, who carefully assessed birth records of individuals

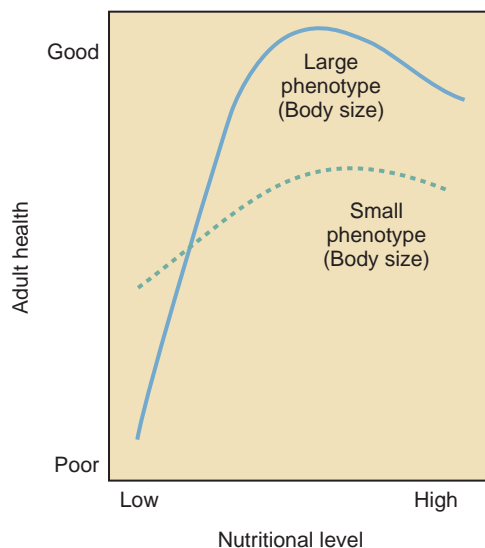


FIGURE 1-1 The potential effects of intrauterine nutrition on subsequent adult health. There are genetic, nutritional, and environmental causes of poor fetal growth leading to a small phenotype. Having a large phenotype at birth has advantages. These data form the basis of the “developmental origins of adult disease” hypothesis (Barker hypothesis). Having a low birth weight increases the risk for diseases and conditions such as hypertension, atherosclerosis, stroke, and diabetes later in life. For example, a nutritionally deprived fetus in utero may develop insulin resistance as an adaptation to preserve glucose supply to the brain rather than releasing it from the circulation to other less important tissues. Later in life, the insulin resistance that was protective in utero could increase the risk of diabetes as an adult. (From Bateson P, Barker D, Clutton-Brock T, et al: Developmental plasticity and human health. *Nature* 430:419-421, 2004. Adapted by permission from Macmillan Publishers Ltd.)

and linked low birth weight (<2500 grams) to the development of hypertension, diabetes, atherosclerosis, and stroke later in life. The association between poor fetal growth during intrauterine life, insulin resistance, and cardiovascular disease is known as the **Barker hypothesis**. The process whereby a stimulus or insult, at a sensitive or critical period of fetal development, induces permanent alterations in the structure and functions of the baby's vital organs is now commonly referred to as **developmental programming**.

Third, another important concept in the life-course perspective is **allostasis**, which describes the body's ability to maintain stability during physiologic change. A good example of allostasis is found in the body's stress response. When the body is under stress (biological or psychological), it activates a stress response. The sympathetic system kicks in and **adrenalin flows to make the heart pump faster and harder** (with the end result of delivering more blood and oxygen to vital organs including the brain). The **hypothalamic-pituitary-adrenal (HPA) axis is also activated** to produce more cortisol, which has many actions to prepare the body for fight or flight.

Normally, as soon as the fight or flight is over, the stress response is turned off. **The body's sympathetic response is counteracted by a parasympathetic response, which fires a signal via the vagal nerve to slow down the heart, and the HPA axis is shut off by cortisol via negative feedback mechanisms.** Negative feedback mechanisms are common to many biological systems and work very much like a thermostat. When the room temperature falls below a preset point, the thermostat turns on the heat. Once the preset temperature is reached, the heat turns off the thermostat. Stress turns on the HPA axis to produce cortisol. Cortisol, in turn, turns off the HPA axis to keep the stress response in check.

This stress response works well for acute stress but it tends to break down under chronic stress. In the face of chronic and repeated stress, the body's stress response is always turned on, and over time will wear out. The body goes from being “stressed” to being “stressed out”—from a state of allostasis to **allostatic overload**. This describes the cumulative wear and tear on the body's adaptive systems from chronic stress. Helpful physiologic mechanisms that initially protect may eventually be harmful.

The life-course perspective synthesizes both the developmental programming mechanisms of early life events and allostatic overload mechanisms of chronic life stress into a longitudinal model of health development. It is a way of looking at life not as disconnected stages, but as an integrated continuum. Thus **to promote a healthy first pregnancy, preconception health should be a priority.** To promote preconception health, adolescent health must be provided to young girls so that as women having children, they are free of diseases such as diabetes, hypertension, and obesity and have been encouraged to eat a healthy diet and to abstain from using tobacco products. **Rather than episodic care that many women now receive, as a specialty we must strive toward disease prevention and health promotion over the continuum of a woman's life.**

IMPACT ON PUBLIC HEALTH

The public health implications of the Barker hypothesis and other life-course events are significant. This is the beginning of an exciting era in medicine where young physicians and other health care professionals can begin to take charge of these events and change our health care delivery system in a very positive way. **Patients should be encouraged to take responsibility for improving their own health, particularly by practicing healthy behaviors early in life.** They should also be encouraged to improve and maintain a healthy “green” environment. Currently there are only a few environmental and behavioral factors that have been clearly identified as part of the Barker hypothesis. Many others are yet to be discovered.

Adaptive developmental plasticity will take place secondary to changes in genes as a result of environmental and behavioral practices. Even the controversial concept of climate change may play a role in this phenomenon. Biological processes are very powerful and frequently unpredictable. Physicians must increasingly strive for a safe, ethical, and value-based practice.

In order to facilitate the improvement of the health and wellness of women and children, four basic principles of practice should guide our strategy: **patient safety, ethical practice, value, and the need for a patient-centered focus on prevention**, as follows.

Patient Safety—The First Principle of Practice

Safety in health care is not a new concept. Facilities have had safety programs in place since the early 1900s, but these programs have traditionally focused on emergency preparedness, environmental safety, security, and infection control. The term *patient safety*, meaning avoidance of medical error, was first coined by the American Society of Anesthesiologists in 1984, when they inaugurated the Anesthesia Patient Safety Foundation to give assurance that the effects of anesthesia would not harm patients.

Medical errors now rank as the fifth leading cause of death in the United States. The Institute of Medicine (IOM) published an alarming report in 1999 called *To Err Is Human: Building a Safer Health System*. This report estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. **Error is defined as failure of a planned action to be completed as intended (e.g., failing to operate when obvious signs of appendicitis are present) or the use of a wrong plan to achieve an aim (e.g., wrong diagnosis, wrong medication administered).** Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually. According to the National Council on Patient Information and Education, “more than 2/3 of all physician visits end with a prescription.” An estimated 39-49% of all medication errors occur at the stage of drug ordering. **Patient noncompliance also contributes to medical errors.**

The U.S. Pharmacopoeia (USP) MedMARx error tracking service estimates that as many as 100,000 medication errors occur annually. Because reporting is voluntary and does not include all medical facilities in the United States, the scope of the problem is likely to be much larger. A preventable adverse drug event (ADE) is one type of medication error. Administering the incorrect drug, an incorrect dose, wrong frequency, or incorrect route may cause an ADE.

A drug that cures one patient's condition may be the one that causes another patient's injury or death due

to an adverse drug reaction (ADR). The latter may account for 1 out of 5 injuries or deaths for hospitalized patients. ADRs commonly occur from an overdose, a side effect, or an interaction among several concomitantly administered drugs. **In order to minimize ADRs, health care providers should avoid the following actions:**

1. **Prescribing unnecessary medications**
2. **Treating mild side effects of one drug with a second, more toxic drug**
3. **Misinterpreting a drug's side effect for a new medical problem** and prescribing another medication
4. **Prescribing a medication when there is any uncertainty about dosing**

In the absence of automated systems, providers should strive to write legibly and use only approved abbreviations and dose expressions. Most health care facilities publish and circulate an acceptable list of appropriate abbreviations, as a means of reducing medication errors.

MEDICAL ERROR REPORTING

According to the U.S. Agency for Healthcare Research & Quality (AHRQ), “Reporting is an important component of systems to improve patient safety.” Incident reporting is an important and inexpensive method to detect medical error and prevent future adverse events. Unfortunately, this method may fail to impact clinical outcomes effectively, because most hospital reporting systems do not capture the majority of errors. **Reporting should be considered a quality improvement process (focused on system failures) rather than a performance evaluation method (blaming individual providers).**

As a founding member of the National Patient Safety Foundation and the National Patient Safety Partnership, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), now more commonly known as The Joint Commission (TJC), has formed a coalition with the U.S. Pharmacopoeia (USP), the American Medical Association (AMA), and the American Hospital Association (AHA) to create patient safety reporting principles. Recognizing that fear of liability discourages error reporting, TJC has advised the U.S. Congress that federal statutory protection must be afforded to those who report medical error. **An anonymous nonpunitive environment will encourage reporting.** Many states have implemented mandatory reporting systems for selected medical errors to improve patient safety and reduce errors. Others consider incident reporting and analysis as peer review activities immune from liability. **The IOM report recommends that health care providers be required to report errors that result in serious harm. Information collected should be made available to the public.** AHRQ publishes case summaries of

reported medical errors and near misses on their website.

DISCLOSURE OF MEDICAL ERROR

The National Patient Safety Foundation (NPSF) was one of the first organizations to address the issue of disclosure. Their position, finalized in November 2000, states, **“When a health care injury occurs, the patient and the family or representatives are entitled to a prompt explanation of how the injury occurred and its short- and long-term effects.** When an error contributed to the injury, the patient and the family or representatives should receive a truthful and compassionate explanation about the error and the remedies available to the patient. They should be informed that the factors involved in the injury will be investigated so that steps can be taken to reduce the likelihood of similar injury to other patients.”

The Joint Commission now requires hospitals to disclose any serious harm caused by medical errors to the harmed parties. Disclosing an error can be very difficult for physicians because they may struggle with intense feelings of incompetence, betrayal of the patient, and fear of litigation. **Studies suggest that physicians with good relationship skills are less likely to get sued. Furthermore, suits are settled more rapidly and for less money if errors are disclosed early. Simple rules for disclosing errors include: admit the mistake, acknowledge the listener's anger, speak slowly, and stop frequently to allow the listener to talk.** Usually, the attending physician is the one who should make the disclosure and offer an apology.

Ethical Practice— The Second Principle

Obstetrics and gynecology encompasses many high-profile areas of ethical concern such as in vitro fertilization (IVF) and other assisted reproductive technologies (ART), abortion, the use of aborted tissue for research or treatment, surrogacy, contraception for minors, and sterilization of persons with a mental illness. Nevertheless, most ethical problems in the practice of medicine arise in cases in which the medical condition or desired procedure itself presents no moral problem. **In the past, the main areas of ethical concern have related to the competence and beneficence of the physician. Current areas of ethical concern should include the goals, values, individual and appropriate cultural preferences of the patient, as well as those of the community at large.** Consideration of such issues enriches the study of obstetrics and gynecology by emphasizing that scientific knowledge and technical skills are most meaningful in a social and moral context.

During the day-to-day consideration of ethical dilemmas in health care, a number of principles or

ideals and the concepts derived from them are commonly accepted and taken into account. Four such principles or ideals are **nonmaleficence, beneficence, autonomy, and justice**; these are generally accepted as the major ethical concepts that apply to health care.

NONMALEFICENCE

The principle of *primum non nocere* or “first, do no harm” originates from the Hippocratic school, and although few would dispute the basic concept, in day-to-day medical practice, **physicians and their patients may need to accept some harm from treatment (such as necessary surgical trauma) in order to achieve a desired outcome.** However, there is an ethical obligation to be certain that recommended medical treatment, surgery, or diagnostic testing is not likely to cause *more harm* than benefit.

BENEFICENCE

The duty of beneficence, or the promotion of the welfare of patients, is an important part of the Hippocratic Oath. Most would see its strict application as an ideal rather than a duty, however. One could save many suffering people in a Third World country by practicing there or by giving a large portion of one's income in aid, but few would consider it a moral duty to do so. On the other hand, **when the concept of beneficence involves a specific patient encounter, the duty applies.** A physician prevented by conscience from participating in the performance of an abortion, for example, would generally be expected to provide lifesaving care for a woman suffering complications after such a procedure—putting her welfare first.

AUTONOMY

The right of self-determination is a basic concept of biomedical ethics. **To exercise autonomy, an individual must be capable of effective deliberation and be neither coerced into a particular course of action nor limited in her or his choices by external constraints.** Being capable of effective deliberation implies a level of intellectual capacity and the ability to exercise that capacity. There are a number of situations in which it may be reasonable to limit autonomy: (1) to prevent harm to others, (2) to prevent self-harm, (3) to prevent immoral acts, or (4) to benefit many others.

The concept of **informed consent** is derived directly from the principle of autonomy, and from a desire to protect patients and research subjects from harm. **There is general agreement that consent must be genuinely voluntary and made after adequate disclosure of information.** As a minimum, when a patient consents to a procedure in health care, the patient should be informed about the expectation of benefit as well as the other reasonable alternatives and possible risks that are known. Table 1-1 provides a useful checklist

TABLE 1-1

THE PREPARED SYSTEM: A CHECKLIST TO GUIDE PATIENT AND PROVIDER IN THE PROCESS OF INFORMED CONSENT

P lan	The course of action being considered
R eason	The indication or rationale
E xpectation	The chances of benefit and failure
P references	Patient-centered priorities (utilities) and cultural preferences affecting choice
A lternatives	All other reasonable options
R isks	The potential for harm from treatment
E xpenses	All direct and indirect costs
D ecision	Fully informed collaborative choice and consent

Modified from Reiter RC, Lench JB, Gambone JC: Consumer advocacy, elective surgery, and the "golden era of medicine." *Obstet Gynecol* 74:815–817, 1989.

(PREPARED) that expands on the minimum information required.

The exercise of autonomy may put considerable stress and conflict on those providing health care, as in the case of a woman with a ruptured ectopic pregnancy who refuses a lifesaving blood transfusion for religious reasons and dies despite the best efforts of the medical team. More complex questions may be raised by court-ordered cesarean deliveries for the benefit of the fetus.

JUSTICE

Justice relates to the way in which the benefits and burdens of society are distributed. The general principle that equals should be treated equally was espoused by Aristotle and is widely accepted today, but it does require that one be able to define the relevant differences between individuals and groups. Some believe all rational persons to have equal rights; others emphasize need, effort, contribution, and merit; still others seek criteria that maximize both individual and social utility. **In most Western societies, race, sex, and religion are not considered morally legitimate criteria for the distribution of benefits, although they too may be taken into account in order to right what are perceived to be historic wrongs, in programs of affirmative action.** When resources are scarce, issues of justice become even more problematic. There are often competing claims from parties who appear equal by all relevant criteria, and the selection criteria themselves become a moral issue. Most modern societies find the *rational* rationing of health care resources to be appropriate and acceptable (Figure 1-2).

OTHER DUTIES OF ETHICAL PRACTICE

Confidentiality is a cornerstone of the relationship between physician and patient. This duty arises from

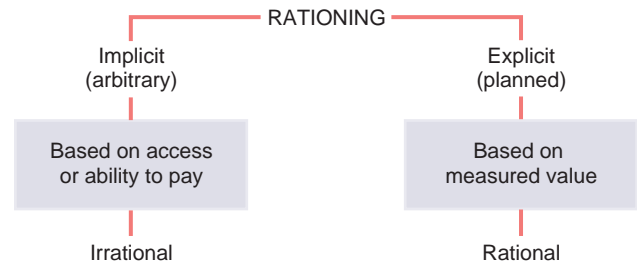


FIGURE 1-2 Representation of arbitrary rationing commonly based on access or ability to pay versus planned clinical resource management based on measured value. *Explicit* rationing is objectionable to many despite the fact that *implicit* rationing still occurs.

considerations of autonomy but also helps promote beneficence, as is the case with honesty. In obstetrics and gynecology, conflicts can arise as in the case of a woman with a sexually transmitted infection who refuses to have a sexual partner informed, or a school-aged child seeking contraceptive advice or an abortion.

There are many other situations in which conflicting responsibilities make confidentiality a difficult issue. The U.S. Health Insurance Portability and Accountability Act (HIPAA) mandates strict rules that physician practices and health care facilities must adhere to regarding the confidentiality and security of patient health care records. Some are concerned that these regulations could restrict the flow of information about patient care and may hinder efforts to improve overall performance.

Caring for a pregnant woman creates a unique **maternal-fetal relationship** because the management of the mother inevitably affects her baby. Until recently, the only way by which an obstetrician could produce a healthy baby was by maintaining optimal maternal health, but as the fetus becomes more accessible to diagnostic and therapeutic interventions, new problems emerge. **Procedures performed on behalf of the fetus may violate the personal integrity and autonomy of the mother.** The obstetrician with a dual responsibility to mother and fetus faces a potential conflict of interest. **Most conflicts will be resolved due to the willingness of most women to undergo considerable self-sacrifice to benefit their fetus.** When a woman refuses consent for a procedure that presents her with significant risk, her autonomy will generally be respected. However, there may be cases in which an intervention that is likely to be efficacious carries little risk to the mother and can reasonably be expected to prevent substantial harm to the fetus. These have occasionally ended in a court-ordered intervention.

Health care is a multidisciplinary activity and respectful and collegial relationships with other health professionals are very important. Although the physician has traditionally been the only decision maker, this situation has often caused concern among other health care professionals. **There is increasing**

recognition that other clinicians involved in health care have a right to participate in any decision making. Physicians have not been as aware of the sensitivities of the nursing profession and other allied health professionals as they should have been. For example, the decision to either operate or not on a newborn with severe spina bifida inevitably leaves nurses with responsibilities to the infant, the parents, and the doctor that may be in direct conflict with their personal values. They may rightly request to be party to the decision-making process, and although the exact models whereby such a goal may be achieved are debatable, physicians must be aware of the legitimate moral concerns of nurses and others involved.

Health care delivery takes place in a very complex environment and **relationships with other interested parties is becoming increasingly important.** Hospitals, health insurance companies, and governments all claim an interest in what services are made available or paid for, and this may prevent individual patients from receiving what their physician may consider optimal care. This poses moral problems not only for physicians on a case-by-case basis but also for insurance companies and society as a whole. **An atmosphere of mutual trust should be sought, earned, and practiced in these relationships.**

Finally, and very importantly, all physicians and other health care providers should be mindful of a potential **conflict of interest** that may occur during practice or during performance of committee work at the local or national level. Even the *appearance* of a conflict between a personal interest and the duty to put patient care interest first can undermine the confidence that patients and the public have in them.

MALPRACTICE AND MALOCCURRENCE

Medical malpractice refers to care that is negligent and below the accepted standard. **When an undesired outcome occurs irrespective of the care that is given, it is referred to properly as medical maloccurrence.** The system of tort law that currently applies to medical malpractice in the United States *distorts* the difference between these two events in many cases. Clearly there is preventable medical error resulting from negligent care, but many of these events are not properly addressed in our system. **Too often medical maloccurrence is judged to be malpractice.**

The interface of medicine and the law raises major ethical issues because legality and morality are not always synonymous. Professional liability insurance premiums for obstetricians are testimony to the relevance of legal issues to obstetric practice. Professional liability is affecting every major decision that is made by the practicing obstetrician and gynecologist, and under these conditions, the “tunnel vision” that ensues may obscure the ability to see clear answers to ethical questions.

Value—The Third Principle of Practice

The mandate from payers (government and employers) and the public to measure and improve the effectiveness and efficiency (value) of health care services is clear. Unfortunately, change based on adoption of national standards derived from evidence-based practice and randomized controlled trials (RCTs) alone may be too expensive and slow to meet this mandate. Furthermore, the results from RCTs may not always establish how diagnostic and therapeutic procedures actually work in clinical practice. **For these reasons, health care organizations, including schools of public health and physician groups, must develop the tools to identify and adopt best practices and improve clinical outcomes locally.**

Value in health care is defined as “clinical outcomes considering the resources used,” or results divided by the costs of care. Figure 1-3 illustrates a collaborative process that may be used to involve the patient in the determination of *value* when decisions about treatments are being made. The past 40 years that have been devoted to the measurement and pursuit of quality improvement have not been successful in terms

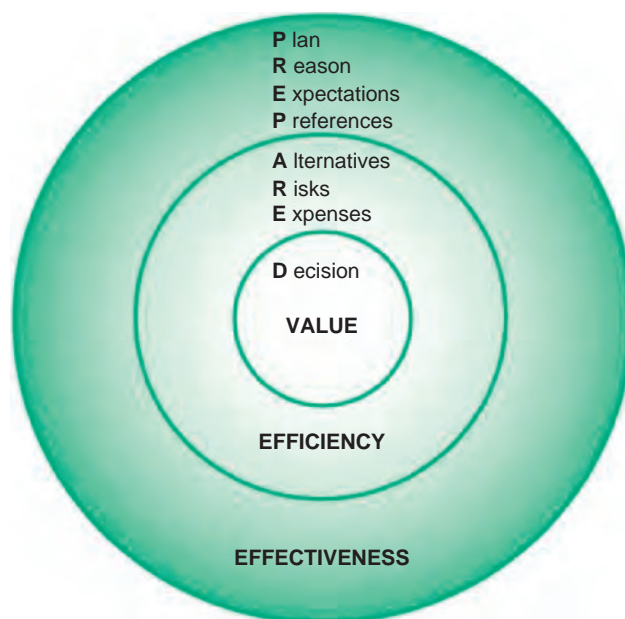


FIGURE 1-3 Involving the patient in the determination of value in decision making. Defining the Plan or Procedure along with its Reason or indication, its evidence-based Expectations, and the patient-centered Preferences for it helps to determine its effectiveness. Further defining of all other Alternatives, the associated Risks and complications along with all Expenses (Costs) determines its efficiency. Making a collaborative Decision based on this process helps to determine the Value of the treatment. (Modified from Gambone JC, Reiter RC, Hagey S: Clinical outcomes in gynecology: hysterectomy. *Curr Probl Obstet Gynecol Fertil* 16(4), 1993.)

SURGICAL SAFETY CHECKLIST

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?

☐ Yes

Is the site marked?

☐ Yes

☐ Not applicable

Is the anaesthesia machine and medication check complete?

☐ Yes

Is the pulse oximeter on the patient and functioning?

☐ Yes

Does the patient have a:

Known allergy?

☐ No

☐ Yes

Difficult airway or aspiration risk?

☐ No

☐ Yes, and equipment/assistance available

Risk of >500 ml blood loss (7 ml/kg in children)?

☐ No

☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist, and surgeon)

☐ Confirm all team members have introduced themselves by name and role.

☐ Confirm the patient's name, procedure, and where the incision will be made.

Has antibiotic prophylaxis been given within the last 60 minutes?

☐ Yes

☐ Not applicable

Anticipated critical events

To surgeon:

☐ What are the critical or non-critical steps?

☐ How long will the case take?

☐ What is the anticipated blood loss?

To anaesthetist:

☐ Are there any patient-specific concerns?

☐ How long will the case take?

To nursing team:

☐ Has sterility (including indicator results) been confirmed?

☐ Are there equipment issues or concerns?

Is essential imaging displayed?

☐ Yes

☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist, and surgeon)

Nurse verbally confirms:

☐ The name of the procedure

☐ Completion of instrument, sponge, and needle counts

☐ Specimen labeling (read specimen labels aloud, including patient name)

☐ Whether there are any equipment problems to be addressed

To surgeon, anaesthetist, and nurse:

☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

FIGURE 1-4 Surgical safety checklist. (Based on the WHO Surgical Safety Checklist: Available at http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf, © World Health Organization 2009. All rights reserved.)

of reducing the high cost of care, particularly in the United States. Transforming health care organizations into high reliability organizations (HROs) that deliver patient-centered value has become the main focus of performance improvement today.

HIGH RELIABILITY IN HEALTH CARE

Recent progress in health care outcomes has been attained by introducing the concepts and tools of HROs into health care delivery facilities. The two industries that have led as HROs have been commercial aviation and nuclear power plants. **In aviation, the adoption of checklists and crew resource management (CRM) has improved commercial aviation safety significantly.** The concepts of CRM (called medical team management in health care) are now being adopted for high-risk procedures in trauma centers and operating rooms. The development of high reliability teams for decision-

making is replacing the older solo “captain of the ship” principle for high-risk, high-consequence health care activities. One checklist developed for health care for use in the operating room (**Figure 1-4**) was tested worldwide by the WHO and resulted in a 47% reduction in surgical mortality and a 36% reduction in inpatient complications. **The use of medical teams in health care has resulted in similar reductions in both mortality and morbidity.** Both of these interventions are relatively inexpensive when compared to the gains and both are highly effective.

Patient-Centered Prevention— The Fourth Principle of Practice

The prevention and mitigation of existing disease has become an extremely important and sometimes

overlooked area of value-based practice. The famous American humorist, Will Rogers, said many years ago that people should only pay their doctors when they are well and not sick. This suggests a frustration that he was reflecting publicly that medical practice had neglected the promotion of wellness, resulting in a high cost of sickness. As health care treatment becomes more expensive and complex, there is a greater incentive for government, private industry, and individuals to invest in preventive services.

There are several good examples of effective preventive interventions that are now available in obstetric and gynecologic practice. **In obstetrics, the newer techniques for mitigating intrauterine fetal damage from chronic stress that may result in short- and long-term morbidity** (see Chapters 7 and 9) **are increasingly successful.** And **in gynecology, the vaccination against human papillomavirus (HPV) infection to prevent cervical cancer** (see Chapters 22 and 38) is a major advance. **Box 1-1** contains a life-course perspective of other early, effective preventive opportunities.

BOX 1-1

LIFE-COURSE PERSPECTIVE OF EARLY PREVENTION OPPORTUNITIES

- Preconception counseling (see Chapter 7)
- Antepartum care and nutrition counseling (see Chapter 7)
- Intrapartum care and surveillance (see Chapters 9 and 10)
- Newborn screening (see Chapter 8 and pediatric care textbooks*)
- Well-baby visits, breastfeeding and nutrition counseling (see pediatric care textbooks*)
- Childhood and adolescent screening and Immunizations (see pediatric care textbooks*)
- Adult preventive health screening (see Table 1-2)

*For example, Kliegman R, Behrman R, Jenson H, et al: *Nelson's textbooks of pediatrics*, ed 18, Philadelphia, 2007, Saunders.

TABLE 1-2

RECOMMENDED PREVENTIVE HEALTH SCREENING FOR WOMEN

Intervention/Procedure	Risk(s)
Pap smear from age 21 irrespective of sexual activity: age 21-29, every 3 yr; age 30-65, every 3 yr with cytology only or every 5 yr with HPV testing added; age >65, only with history of significant CIN After total hysterectomy (corpus and cervix) cytology not needed (see Chapter 38)	Cervical dysplasia/cancer
Annual breast exam ages >39 and every 1-3 yr age 20-39; high risk women should consider annual exam; screening mammography annually starting at age 40; USPSTF recommends starting at age 50; breast self-exam not universally recommended (see Chapter 29)	Breast cancer
Smoking cessation counseling, warning about second-hand smoke exposure	Lung cancer, heart disease, other health risks associated with smoking
Sigmoidoscopy or colonoscopy (preferred) every 3-5 yr after age 50	Colorectal cancer
Height and weight measurement for BMI calculation (see Box 2-2)	Overweight and obesity
Regular blood pressure screening (every 2 yr)	Hypertension and stroke
Cholesterol/lipid profile every 5 yr until age 65	Heart disease
Total skin inspection and selective biopsies	Skin cancer (sun exposure)
Diet and exercise counseling; BMD testing for all women > age 64, or younger if at least one risk factor for osteoporosis (see Chapter 35)	Osteoporosis, fracture, and deformity
Blood sugar study with family history, obesity, or history of gestational diabetes	Diabetes mellitus; other comorbidities associated with obesity
Cervical sampling for <i>Chlamydia</i> , <i>N. gonorrhoeae</i> , syphilis, and HIV based on history of high-risk behavior (see Chapter 26)	Sexually transmitted infections
TSH starting at age 50 (see Chapter 35)	Thyroid disease
PPD of tuberculin for high-risk women	Tuberculosis

BMD, Bone mineral density; BMI, body mass index; CIN, cervical intraepithelial neoplasia; HIV, human immunodeficiency virus; HPV, human papillomavirus; Pap, Papanicolaou test; PPD, purified protein derivative; TSH, thyroid-stimulating hormone; USPSTF, United States Preventive Services Task Force.