ABSTRACT: Recommendations to patients about testing should be based on current medical knowledge, a concern for the patient’s best interests, and mutual consultation. In addition to establishing a diagnosis, testing provides opportunities to educate, inform, and advise. The ethical principles of respect for autonomy (patient choice) and beneficence (concern for the patient’s best interests) should guide the testing, counseling, and reporting process. Clear and ample communication fosters trust, facilitates access to services, and improves the quality of medical care.

In the practice of medicine, clinical evaluation is enhanced by a broad range of tests. Recommendations to patients about testing should be based on current medical knowledge, a concern for the patient’s best interests, and mutual consultation. Patient testing embodies many scientific and human ideals. From an ethical perspective, the most important principles involve a trusting patient–physician relationship emphasizing beneficence (the benefits the patient may derive from testing) and respect for autonomy (an appreciation that patients make choices about their medical care). Issues of nonmaleficence (using tests when the consequences of the test are uncertain) and justice (applying tests to low-risk groups) also may be important (1).

Rapid technologic development and the need to consider legal and sociocultural factors as well as medical knowledge have increased the complexity of the decision-making process. The physician often is in the position of ordering tests—for human immunodeficiency virus (HIV) or genetic markers, for example—that may, unlike a urinalysis or a hemogram, have a profound effect on the patient, her partner, her family, and society in general. This new level of complexity requires the specification of both medical and ethical guidelines for decisions about patient testing. This Committee Opinion provides ethical guidance for decisions about ordering tests, counseling patients, and reporting results.

Ordering Tests

- The physician and the patient have a shared responsibility. The quality of medical care improves when there is clear communication and mutual understanding between physician and patient. It is the responsibility of the obstetrician–gynecologist to communicate effectively and to develop skills that promote a patient–physician relationship that is characterized by trust and honesty. Similarly, it is the responsibility of the patient to provide accurate information about her lifestyle, health habits, sexual practices, and religious and cultural beliefs when these factors may affect medical judgment. In decisions about testing, physicians should be guided by scientific knowledge. Care must be taken to avoid subjective assumptions based on bias that could affect the appropriateness of testing (2).
Testing should be performed primarily for the benefit of the patient. Testing at the request of third parties—partners, health care providers, members of the patient’s extended family, employers, or health insurers—is justifiable only when the patient or her valid proxy understands the potential risks and benefits and gives consent (3). Examples of this type of testing include genetic tests to assist family members with reproductive decisions, HIV tests to fulfill conditions for the purchase of life insurance, and requests for patient testing after the occupational exposure of health care workers.

The decision to offer or to withhold a test should not be made solely on the basis of a physician’s assumptions about the patient’s expected response to test results (4). Prejudgments about a patient’s wishes regarding fetal abnormalities, for example, should not preclude her being offered prenatal testing. The patient should join with the physician in deciding the amount of diagnostic information that is appropriate for making intelligent choices about preventive care and treatment options. The physician is not, however, ethically obligated to perform every test a patient requests, particularly if disease prevalence and risk factors are low, generating a high false-positive risk.

The patient must be informed prospectively about policies regarding use of information and legal requirements. The patient must be told what will be communicated, to whom, and the potential implications of reporting the information. If, for example, a patient is concerned about posting HIV test results in the medical record and who may have access to the results, she may choose instead to use an anonymous testing procedure available through another laboratory. In some situations, reporting of results is mandated by law. Physicians should be familiar with the laws regarding mandatory testing and reporting requirements in their own jurisdictions.

The physician and patient should discuss concerns about cost containment and reimbursement. The mutual goal of physician and patient should be to avoid both undertesting and overtesting. Contemporary focus on the economics of health care has created worries for both physician and patient about access to care, limitations to testing, appropriateness of use, and the impact of financial constraints on quality of care. Testing done with low probability of improving patient diagnosis or testing solely for the sake of professional liability concerns should be avoided. Open communication about cost concerns and perceived benefit is the best way to alleviate suspicion and to promote trust.

Pretest and Posttest Counseling

Testing that may have multiple medical or psychosocial consequences requires specific counseling. The extent of counseling beneficial to each patient will vary depending on the individual and on the implications inherent in the potential test results. With simple tests like urinalysis, it is sufficient to provide information about the nature and purpose of the test and how the results will guide management. Tests that may have multiple medical or psychosocial ramifications require comprehensive explanation of the process, the goals, and the implications (4). Counseling can be appropriate for genetic testing and maternal toxicology assays, for example, because of the potential for psychologic, social, and economic effects. Tests with low positive predictive value, such as cervical cytology and mammography, can generate the need for additional and more extensive testing. Testing for HIV or inherited breast cancer mutations may limit future insurance coverage.

In some cases, the potential benefits—including societal benefits—of certain tests may lead some to recommend alternative schemes for counseling and consent in order to maximize the rate of testing. The U.S. Centers for Disease Control and Prevention, ACOG, and the American Academy of Pediatrics have endorsed an “opt-out” protocol with patient notification for prenatal HIV testing (5–7). The use of patient notification provides women the opportunity to decline testing but eliminates the requirement to obtain specific informed consent.

Autonomy of the individual in shared decision making should always be respected. It is essential in the informed consent process that subsequent election of the patient to forgo a recommended intervention (informed refusal) be carefully documented in the patient’s medical record along with the patient’s reason for refusal. Both pretest and posttest counseling facilitate women’s access to appropriate health care. Pretest counseling includes both medical considerations and issues such as the availability of emotional support while waiting for test results. Posttest counseling offers an opportunity to provide access to resource networks and community-based services.

Referral may be needed for comprehensive counseling. If time constraints or lack of technical expertise make it difficult to offer comprehensive counseling in a particular practice, appropriate options include either 1) referral to a specialized center for both counseling and testing, or 2) referral for counseling only, with return to the original physician for testing and medical follow-up.
Confidentiality and the Reporting of Test Results

- Information ordinarily may not be revealed without the patient's express consent. Physicians have an obligation to be familiar with federal privacy protection legislation (Health Insurance Portability and Accountability Act) (8). Guidance is provided here for the ethical duty to maintain confidentiality. Maintaining confidentiality is intrinsic to respect for patient autonomy and permits the free exchange of information that is relevant to medical decision making. Situations may arise, however, in which a physician has competing obligations: protecting the patient's confidentiality or disclosing test results to prevent harm to a third party. In these situations, every avenue of communication should be explored first in discussions with the patient about rights and responsibilities. Consultation with an institutional ethics committee or a medical ethics specialist may be helpful in weighing benefits and harms of disclosure. Legal advice may be prudent.

- A violation of confidentiality may be ethically justified as a last resort. A violation of confidentiality may be justifiable only when legally required or when all of the following conditions have been met: 1) there is a high probability of harm to a third party, 2) the potential harm is a serious one, 3) the information communicated can be used to prevent harm, and 4) greater good will result from breaking confidentiality than from maintaining it. Case law has not yet been developed to address the grey area where, on rare occasions, legal obligations to protect patient confidentiality and ethical and professional obligations to act for the benefit of the patient may conflict.

Conclusion

In addition to establishing a diagnosis, testing provides opportunities to educate, inform, and advise. The ethical principles of respect for autonomy (patient choice) and beneficence (concern for the patient’s best interests) should guide the testing, counseling, and reporting process. Clear and ample communication fosters trust, facilitates access to services, and improves the quality of medical care.

References


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