TALKING ABOUT CLINICAL PRACTICE GUIDELINES: HOW MUCH SHOULD PATIENTS BE TOLD?

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Recent clinical guidelines have been developed to help physicians make effective and cost-efficient health care decisions. These evidence-based guidelines are one among many tools available to help today's practicing physicians make decisions regarding their patients' care. During the 1970s and 1980s, older "guidelines" such as the *Washington Manual* were developed. In them, physicians found treatment options for virtually all diseases, and physicians often followed them to the proverbial letter. The new guidelines, however, vary widely in scope. At one extreme are general guidelines, such as guidelines from the American Pain Society [1], which state principles and policies; at the other are clinical pathways, such as a hospital's acute myocardial infarction (AMI) pathway, which details everything that is to occur during every day of a patient's hospital stay following an AMI.

In some cases, guidelines make it easier for a clinician to provide what she thinks is the best care without referring each patient to a battery of specialists. Guidelines may also help her avoid using her limited time to closely review all the data relevant to a specific clinical scenario. Generalists, for example, may find it difficult to remain abreast of advances in a variety of fields and may find guidelines to be invaluable continuing education resources. By using evidence-based guidelines and best practices developed by expert panels of subspecialists, the primary care physician can apply the latest discoveries and expert opinion of leaders in the field to the care of her patients. She can both fulfill her fiduciary responsibility to her patients and eliminate unnecessary consultations.

Furthermore, if a clinician agrees with a guideline, she can use it to support her decisions if a patient resists her recommendations. For example, when choosing a pharmaceutical agent to treat a patient with bronchitis, a physician may be perfectly satisfied with the antibiotic choices offered by her health system's formulary. She knows that the formulary decisions were made by a carefully selected committee concerned about the development of resistance as well as issues of effectiveness and cost. If her patient protests that he wants an antibiotic he recently learned about through the media, which is newly approved, very strong, and requires fewer days of treatment than older antibiotics, she can use the formulary to explain her choice, citing the evidence on which the guideline was based.

When clinicians work within guidelines, however, the potential for ethical dilemmas arises. The central ethical dilemma faced by today's clinicians is the difficult task of balancing traditional obligations to the patient with new and less well-understood obligations to conserve resources [2]. When clinicians are asked both to advocate for their patients' well-being and to be responsible stewards of health care resources, they must fulfill dual and sometimes incompatible roles [3,4].

Ethical Questions Raised by a Case Involving Screening Mammography

Clinical guidelines are often invaluable tools for providers; however, following them may cause physicians to feel forced into awkward positions. Consider the following scenario concerning the use of guidelines for screening mammography. What are Dr. Miller's options?

> Sheila Arensen, a 40-year-old librarian who is married and has 3 children, has an initial visit with Dr. Miller for routine health maintenance; she has no complaints. During the course of their conversation, Dr. Miller learns that Mrs. Arensen has not yet had a screening mammogram. In reviewing her history, he also learns that no one in her family has had breast cancer; she has no other factors that increase her risk for developing breast cancer.
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> He is aware that some current guidelines, such as those from the American Cancer Society, suggest a screening mammogram at age 40 [5]. However, he belongs to a staff-model managed care organization (MCO) that recommends beginning mammograms at age 50 for women who are at average risk for breast

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> cancer, and at age 45 for high-risk women. Radiology will not schedule mammograms for patients under age 50 unless they meet the high-risk criteria.

What should Dr. Miller do if he agrees with those organizations that recommend beginning the use of mammograms to screen women for breast cancer at age 40? What should he do if he has reason to doubt the evidence on which his MCO's guideline was based? What if Dr. Miller questions the objectivity of the organization that created the guideline?

Dr. Miller does not face a medical decision about the applicability of the guideline. It clearly applies to his patient, and Dr. Miller is also certain that he will not be able to obtain a mammogram through the usual channels. Dr. Miller must decide, therefore, whether or not to discuss the guideline with Mrs. Arensen and to what extent he should involve her in the ethical choices that he must make.

Balancing Physician Obligations

In this case, Dr. Miller is being asked both to fulfill his fiduciary responsibility to Mrs. Arensen and to participate in quality improvement initiatives within his organization. Should he discuss the guideline with Mrs. Arensen? Should he inform her about the lack of consensus regarding its recommendations?

These difficult questions arise from the central ethical dilemma of the clinician's duty to the patient versus another, less well-defined duty to future patients and to society. The physician's obligation to the patient is never absolute, and this dual role is not a unique ethical problem. Physicians have always had some obligation to society, and they have always been asked to balance this obligation against an obligation to the patient. For example, there is general agreement that physicians have a duty to protect patient confidentiality. However, society also requires physicians to break that obligation if a patient shows evidence of violence or has a sexually transmitted disease. Therefore, Dr. Miller's choice between following a guideline that will best serve society and acting in what he perceives to be Mrs. Arensen's best interest is not a new dilemma. However, the recent focus on using guidelines to deliver the best care for the greatest number of people does create new challenges for physicians.

Obtaining Consent for Proven Versus Unproven Interventions

In cases involving proven treatments or tests, the law and norms of physician responsibility mandate that physicians seek a patient's consent before performing them [6]. If Dr. Miller decides to order a mammogram, he should first provide Mrs. Arensen with the information necessary for her to make a choice that is free of influence and coercion [7–9]. Mrs. Arensen would then have the right to refuse the procedure. However, because the MCO's guidelines do not recommend a screening mammogram for Mrs. Arensen, the issue is more complicated. If Dr. Miller is obligated to obtain Mrs. Arensen's consent before ordering a mammogram, is he also obligated to obtain her consent *not* to order it?

Dr. Miller has an obligation to discuss all proven diagnostic and treatment options. If a mammogram would clearly produce effective results in Mrs. Arensen's case, Dr. Miller would be obligated to discuss it. However, he need not discuss a mammogram if it would be clearly ineffective or potentially harmful. For example, if Mrs. Arensen were only 19 years old, Dr. Miller need not, and indeed should not, discuss mammography because such information would not be clinically useful to her.

Therefore, Dr. Miller's choice would be straightforward if screening mammography were proven to be either clearly effective or clearly ineffective for women in Mrs. Arensen's age-group. The problem Dr. Miller faces, however, is that in Mrs. Arensen's case a mammogram is neither. Although a mammogram may benefit Mrs. Arensen, a false-positive result would require further tests and possibly a biopsy, and the costs associated with these procedures must also be considered. Therefore, because the benefits of ordering a mammogram for Mrs. Arensen are disputable, and because her health plan will not pay for the procedure, Dr. Miller must decide whether or not to discuss the guideline with Mrs. Arensen and whether or not to discuss his uncertainty about it.

Discussing Guidelines: When and How Much Should You Tell Your Patients?

Although there is no easy solution to the dilemma of balancing obligations, we recommend three general criteria for deciding how much information physicians are obligated to share with their patients: the reasonable person standard, the subjective standard, and what we will call "the equipoise standard." Although we discuss each criterion individually, in actual clinical practice they are not discrete categories for evaluating a physician's responsibility to disclose information to her patients. Physicians should discuss the diagnostic or treatment option in question if any of the criteria apply.

The Reasonable Person Standard

Given the increasingly rapid rate of advances in health care technology, many patients may not be aware of newly approved treatments or diagnostic tests. Although

information is becoming readily available to patients, physicians should assume that their patients do not know about a new test or treatment option unless a health care provider discusses it with them. According to the reasonable person standard, a physician should discuss a test or treatment with her patients if she believes that a reasonable person would expect to be informed that it is an option.

Because a duty to tell the truth is implied in the physician-patient relationship, physicians must tell patients the truth whether or not patients expect them to. This duty to tell the truth, in turn, is mandated by the broader duty of a physician to respect her patients [10,11]. Because disclosing information to patients can therefore be seen as a mark of respect for them as people, physicians may also be obligated to discuss treatment and testing options with patients if failing to do so would constitute conscious deception on the part of the physician.

Consciously withholding information about a test or treatment may significantly damage the public's trust in the medical profession [12]. More importantly, a lack of trust could weaken the foundation of the physician-patient relationship and reduce the efficacy of the therapeutic alliance. Therefore, to the extent that physicians have a duty to preserve the public's trust in the profession [13], they may also have a duty to discuss even futile treatments if failure to do so might weaken that trust. If a patient believes that her physician would have discussed an intervention if there were even a marginal chance of its efficacy, failure to do so would violate the reasonable person standard. In the case of Mrs. Arensen, Dr. Miller should discuss the disputed mammography guidelines if he believes that a reasonable person would expect to be informed that the procedure is an option, despite it not being covered by her health plan. Failure to discuss the mammogram guidelines may cause Mrs. Arensen to believe that early screening for breast cancer is of no benefit to her.

The Subjective Standard

Although the reasonable person standard requires that a physician discuss a procedure or treatment if a reasonable person would want to know about it, the subjective standard requires that she discuss it if she believes that the patient in question would desire that information. This criterion is more stringent and requires not only that physicians disclose the options that most patients would want to know about, but also those options that each individual patient would believe important. Dr. Miller should discuss the mammogram with Mrs. Arensen if he has reason to believe that she would want information about it. This might be the case if she had indicated that she was particularly worried about developing breast cancer.

The Equipoise Standard

In some cases, the health care community (ie, physicians, researchers, ethicists, patients) may be uncertain about the effectiveness of a test or treatment. Benjamin Freedman's concept of "equipoise" provides an eloquent description of such situations. Freedman originally used the term in the very different setting of clinical research to capture the uncertainty about efficacy that pervades much of modern medical practice [14]. Reasonable, well-informed people often disagree about the merits of a medication, test, or procedure. Under these circumstances, care providers identify as accurately as possible the best treatment by relying on research and consensus. This uncertainty is not an exception or aberration; rather, it is the usual state of the evolving practice of medicine.

Dr. Miller first must assess whether or not equipoise truly exists in Mrs. Arensen's case. He must decide, for example, whether the MCO's guideline is derived from sound data and reviewed by experts, or whether it is motivated by financial concerns [15]. Dr. Miller might also consult with physician colleagues whose judgment he respects to assess whether or not equipoise exists. Finally, Dr. Miller should have a working understanding of the guidelines of national organizations.

After careful review, Dr. Miller may decide that a state of uncertainty, or equipoise, exists. To apply Freedman's term to this case, we might say that because the medical community is divided by uncertainty about the use of mammography, Dr. Miller must assess Mrs. Arensen's preferences in order to decide, with her, if the procedure offers what she believes to be a significant benefit. That is, because science has been unable to establish a definitive answer about the efficacy of mammography in Mrs. Arensen's case, it is especially important for Dr. Miller to elicit her opinions. Mrs. Arensen's concerns, fears, and priorities should drive decisions when no clear scientific consensus exists.

Conclusion

The physician-patient relationship is built on trust and the expectation that physicians will conduct themselves honestly and with respect for their patients. Unfortunately, managed care may threaten the trust that patients have in their physicians. It is not clear how and why the advent of managed care has eroded patient trust, but this danger appears to be real [16]. Therefore, it is more important than ever for physicians to

communicate as clearly as possible about options and potential tests and treatments.

Physicians can best accomplish this difficult goal by considering what Howard Brody has described as the ideal of "transparency" [17]. The informed consent process, he argues, should ideally be one of open and honest discussion between physician and patient. Brody urges physicians to make their thinking, particularly their doubts and uncertainties, as clear to their patients as they possibly can.

Thus, Dr. Miller should be prepared—as should all physicians in similar circumstances—to discuss the mammography guidelines openly and honestly with Mrs. Arensen and to share any doubts he has about them with her. As we have suggested, a physician might withhold discussion only if she believes that most patients would not expect to be informed about a noncovered intervention or that an individual patient would not expect to be informed about a test or treatment, or if there is general agreement in the medical community that the noncovered intervention does not offer significant benefits to the patient. In all other circumstances, physicians should adhere to Brody's ideal of transparency. Not only do such discussions offer respect for patients as persons, but they also maintain trust in the medical profession and allow physicians to continue their participation in quality improvement efforts.

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