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The Right Intentions but Wrong Prevention: On Informed Consent for Preventive Services of Controversial Effectiveness

by Michael D. Fetters, MD, MPH, MA

Physicians following the literature cannot help but notice a steady stream of calls for informed consent dialogue about the risks and benefits of a preventive service of controversial effectiveness. Authors of studies with conflicting or inconclusive results often make recommendations such as, "The clinician should have an informed consent dialogue with the patient about the potential risks and benefits of testing." While these authors may have the right intentions, it is the wrong prevention if services of unknown effectiveness monopolize the physician's and patient's attention. Here, I argue against clinicians routinely suggesting tests of controversial effectiveness to patients. Furthermore, researchers who have insufficient evidence to make clear recommendations about the effectiveness of a preventive service should refrain from "ambiguity dumping" on primary care physicians and their patients.

Barriers to Service

Primary care physicians are already under fire for failure to meet benchmark delivery rates of preventive services of known effectiveness [1-6]. One barrier to delivery of such services is the sheer number of procedures that are recognized by The United States Preventive Services Task Force (USPSTF) and could be provided to each patient [7]. Interventions of proven effectiveness as defined by the USPSTF are too numerous to be delivered in the allotted time of a health maintenance examination [8]. For example, there are no less than 38 preventive services with an A or B recommendation from the USPSTF for an asymptomatic woman in her 40s, and 27 preventive services for an asymptomatic man in his 40s (Table 1) [7]. For patients with risk factors, the number of effective preventive services increases.

Physicians have always had a compelling ethical imperative to act beneficently, and this obliges them to provide these effective services to their patients. Similarly, the principle of nonmaleficence directs physicians to not omit services of known benefit. Such errors of omission can result in harm, as in the case of a woman with a delayed diagnosis of breast cancer due to a failure to screen. Inasmuch as beneficence (doing good for patients) and nonmaleficence (not harming patients) share the goal of advancing patients' best interests, I will treat these as one overriding concern in the arguments below.

A second barrier to delivery of preventive services of proven effectiveness is the need for physicians to address the patient's agenda. As illustrated by the competing demands model, many other interests compete with prevention delivery. Among these interests are medication refills, management of chronic problems, supporting patients

under stressful circumstances, and providing treatment or other support to family members [9]. In the interest of providing patient-centered care and working on a shared agenda with the patient, there is an ethical imperative to address the patient's concerns to the fullest extent possible.

Tests of controversial effectiveness stand as a third obstacle during prevention visits. The ethical principle of autonomy and respect for persons supports an informed consent discussion of all tests. In the case of a controversial test, it can be argued that there is no evidence-based "best" answer to whether a patient should receive a service. Consequently, the patient's values and preferences have particular bearing on whether he or she has the test. For example, PSA screening has not conclusively been shown to change outcomes of prostate cancer treatment. Moreover, there are significant risks from positive screening results such as anxiety; and risks from treatment include incontinence and sexual dysfunction. Patients frequently have opinions about these risks and benefits, and the ethical arguments for involving patients in such discussions about their opinions and concerns are compelling [10].

In sum, there are 3 competing ethical considerations: providing benefit to the patient through delivery of effective preventive services (and avoiding harm through errors of omission), meeting patient needs by using a patient-centered approach, and respecting patient decision making through an informed consent dialogue about preventive services of controversial effectiveness. Each of these has ethically compelling merit. In an ideal world, physicians would address all 3 morally worthy agendas. Unfortunately, these ethical considerations compete with each other due to a physician's limited time [8].

Given time constraints, it is frequently not feasible to provide all the effective services, address the patient's agenda, and conduct an informed consent dialogue about services of controversial effectiveness. I contend that providing services known to be effective has greater moral weight than providing services of controversial effectiveness. Beneficence claims supporting provision of the effective preventive services outweigh those associated with provision of controversial services.

While the above seems straightforward, patients sometimes request preventive services of controversial effectiveness as part of *their agenda* with physicians. In these circumstances, clinicians need to conduct an informed consent dialogue and help patients make a choice [10]. The ethical basis for providing a test of controversial effectiveness becomes stronger when associated with patient-centered care and respect for patient decision making. But such discussions run the risk of causing harm if they are so long that they preclude delivery of the effective preventive services.

Hence, I argue that the "best ethical practice" with regard to preventive services of controversial effectiveness is for clinicians not to address these issues unless raised by the patient. If an informed consent dialogue about a controversial test does occur, these dialogues should be kept as short as possible in order to save time for delivery of effective preventive services (and reduce harm by minimizing errors of omission). Keeping these discussions short will help maximize time for addressing other concerns

raised by the patient. Patients need a sufficient understanding of the risks and benefits of tests of controversial effectiveness, but prolonged deliberations have an ethical cost.

Critics of this position might argue that such controversial tests may have a yet-undiscovered benefit and that the real flaw is the lack of well-designed research. Of course, the alternate possibility is that such controversial tests truly are not effective and subsequent, better-designed research will prove their ineffectiveness. A dialogue with the patient, no matter how detailed or comprehensive will not change the quality of the existing data for deciding whether testing will lead to a statistically improved outcome. In the absence of effectiveness data, a coin toss might be as likely to yield the better choice.

The implications of this analysis are 2-fold. First, clinicians should de-emphasize preventive services of controversial effectiveness. Second, investigators who conduct research that yields equivocal results about a service's effectiveness should be judicious in their time allotment for an informed consent dialogue by clinicians and patient. Editors and reviewers of manuscripts should discourage such "ambiguity dumping" during the publication process.

Eliminating the expectation that doctors and patients have informed consent dialogues about tests of controversial effectiveness unless raised by the patient will help protect the limited time available for prevention. Despite well-meaning intentions, clinicians should be liberated from routine expectations to spend time on unproven services, as this is the wrong prevention to dominate the agenda.

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Michael D. Fetters, MD, MPH, MA, is an associate professor in the Department of Family Medicine at the University of Michigan and director of the Japanese Family Health Program at the University of Michigan. *His involvement in this work was made possible by the Robert Wood Johnson Generalist Faculty Scholars Program and the Michigan Consortium of Family Practice Research.*