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Could Good Care Mean Withholding Information from Patients?

Commentary by Benjamin D. Long and Andrew G. Shuman, MD

Every morning for three weeks, Isalita has sat at her patient Janet's bedside. As a third-year medical student on an oncology rotation, Isalita has the most time of anyone on the health care team to get to know her patients. Janet has talked to Isalita about her past medical experiences, both good and bad, saying that she appreciates physicians' being open and honest with her about her medical condition. She wants the chance to understand what is going on, she tells Isalita, even if in the end she asks for and takes the physician's recommendation.

Janet's oncologist, Dr. Haveford, has been seeing Janet since her initial diagnosis and treatment for breast cancer. They have a trusting and comfortable relationship with one another. Dr. Haveford pays particular attention to each of his patient's preferences and values. In Dr. Haveford's experience, Janet, when presented with a number of choices, has appeared uncertain and ultimately asked him what he thinks would be best for her.

Janet's cancer has now metastasized. Other than some clinical trials for which she might be eligible, Dr. Haveford does not think that more treatment will slow her cancer's progress, even though some available drugs might extend her life, and he believes that going through any of the available trials would likely diminish Janet's remaining quality of life. Moreover, he does not want to overwhelm her with details about clinical trial options, risks, and potential benefits. Knowledgeable and responsive patient-centered care in this instance, he thinks, means not telling her about clinical trials.

When Dr. Haveford discusses Janet's treatment options with her, Isalita is dismayed that he only presents Janet with a recommendation to pursue conventional options in combination with palliative treatment. She is uncomfortable with the idea of not sharing the clinical trial options with Janet, but she does not want to appear to be trying to undermine Dr. Haveford's authority or question his judgment.

Commentary

Is Dr. Haveford's withholding information about clinical trials appropriate in this case and what are criteria upon which we might decide? Additionally, what should Isalita do?

Roles of Clinical Trials in Caring for Patients

To resolve these questions, we must briefly re-examine the purpose of clinical trials. Clinical trials are research experiments designed to test the safety and/or efficacy of an unproven treatment. In order to justify the administration of unproven treatment modalities and the procedure of randomization, which might expose subjects to risk, the research ethics community has invoked the concept of clinical equipoise, whereby the efficacy or superiority of each trial arm is legitimately unknown [1]. Clinical trials, especially in early phases, are designed to help future patients, not the subjects themselves. This might create a "therapeutic misconception," in which study subjects mistakenly believe that their participation implies that substantive benefit is likely [1]. The therapeutic misconception might persist among the majority of subjects despite even rigorous efforts to obtain informed consent [2]. This misconception likely persists because the distinction between clinical practice and research is blurred, especially in research designed to evaluate the efficacy of a therapy. The goals of clinical medicine and research are inexorably at odds with one another. As mentioned in *The Belmont Report*, while the purpose of clinical medicine is to provide diagnosis and treatment, the purpose of research is to test a hypothesis [3]. Thus, an *a priori* responsibility of clinical researchers enrolling patients as subjects is to dispel this misconception by informing them about the fundamentally different goals of clinicians and researchers.

Although clinical trials are not always designed to benefit study subjects, health care professionals (and clinical researchers) have an obligation to future patients. Physicians arguably have the responsibility to maximize the well-being of not only their patients, but also society at large. However, there is a fundamental intimacy to the doctor-patient relationship that is not easily transcended by larger societal obligations and demands. And clinical trials are distinct in that they necessarily encroach on the primacy of the physician-patient relationship; in essence, patients become subjects, so patients and families are no longer the center of care.

Despite these shortcomings, there might be many legitimate reasons why a physician might suggest that a patient participate in a clinical trial. Patients facing potentially imminent death might want to participate in clinical research because they view any additional relative risk as minimal. Miller and Brody argue that clinical trials can be ethical under two conditions: when there are only slight risks of study participation compared to standard practice (prefaced upon clinical equipoise), or if they offer the (remote) possibility of therapeutic benefit for patients who have exhausted all standard therapy other than comfort care [4]. So-called "sacrificial altruists" might even choose to participate in order to advance our collective understanding for future benefit, even if participation could result in direct harm. A commonly reported wish of many patients near the end of life includes the desire to help future patients [5]. One can convincingly argue that, rather than needing protection from herself, Janet similarly deserves to be considered as a trial participant. However, should physicians always be obliged to disclose information about clinical trials to their patients?

Shared Decision Making

Hippocrates, long regarded as the father of modern clinical medicine, once encouraged physicians to "[conceal] most things from the patient while attending to [him]; [to] give necessary orders with cheerfulness and serenity…revealing nothing of the patient's future or present condition" [6]. Until recently, physicians routinely assumed this kind of paternalistic role, using their professional expertise to make decisions they judged to be in the best interests of their patients. In today's lexicon, however, "paternalism" has become more of a moniker for arrogance and authoritarianism [7]. More collaborative approaches to maintaining patient-physician relationships are now considered appropriate. Roeland and colleagues [7] describe Kon's concept of the "shared decision making continuum" (with "physician-driven care" at one extreme and "patient-driven care" at the other [8]), in which the physician's role is "determining the appropriate level of patient autonomy when addressing treatment decisions" [9]. We consider this a useful approach for considering this case.

Shared decision making requires physicians to consider a spectrum of information sharing. Physicians do not generally want to share irrelevant or unhelpful information with patients, but they do want to invite patients to help them assess what, according to their values and ways of seeing the world, would constitute relevant and helpful information. There are several exceptions to informed consent that allow physicians to withhold information from their patients. Physicians might invoke the principle of therapeutic privilege (or therapeutic exception) in extraordinary circumstances when they believe that withholding information offers substantive therapeutic benefit, such as preventing acute emotional distress that compromises health [10]. Furthermore, even if disclosure would not cause direct harm, physicians are not compelled to recommend anything they do not believe confers medical benefit or is not relevant to the decision at hand. Shared decision making works best when physicians have excellent interpersonal communication skills and a high level of emotional intelligence, as a physician must titrate and distill information according to his or her interpretation of responses from patients about their values and goals of care.

By withholding information from Janet, Dr. Haveford seems to be acting appropriately. While it is not clear if Janet would suffer direct harm from the disclosure of clinical trial options, Dr. Haveford does not believe that clinical trials will offer a therapeutic benefit (nor is that how trial candidacy is established). In fact, he is concerned that a clinical trial and aggressive treatment could actually harm Janet, either directly or indirectly. Dr. Haveford has established a rapport with her and believes that, while she wants to remain informed, she does not want to be burdened with choices and would rather delegate her responsibility to make certain medical decisions to entrusted clinicians. Dr.

Haveford is acting in accordance with his best impression of Janet's wishes regarding how much information she receives and how medical decisions are made. Since such decision-making practices would vary depending on a patient's values, understanding patient values is crucial in determining how much information to disclose. Of course, we create a tautology if we are to require a clinician to *know* exactly how a patient would react to information that has yet to be disclosed; as in all aspects of medicine, judgment and experience are critical.

Shared decision making is especially important in end-of-life care, when the consequences of medical decisions become magnified. Under the informed choice model, many patients choose the more aggressive treatment, perhaps because they view anything less as giving up [11]. The idea that one should not give up, but rather fight using any means necessary, is a common belief that has permeated our medical culture. But there is little evidence that such treatment leads to better outcomes. Indeed, a randomized study involving terminal lung cancer patients found that those receiving early palliative care integrated with standard oncologic care survived two months longer, had a better quality of life, and experienced less depression than those who received standard care alone [12]. Shared decision making has been shown to encourage patients to consider less aggressive care [13], which might result in better health outcomes.

Also, as Roeland and colleagues put it,

> it has been our observation that, as patients approach death, medical providers frequently defer these [life-or-death] decisions to patients and/or loved ones…hoping that the patient and/or family will say, "No more." However, this unintentionally causes the patient and/or loved ones to feel as if they are "pulling the plug"…. [P]atients and/or loved ones want the medical providers to make the decision so they are not responsible for "killing" themselves or a loved one [9].

A physician actively participating in a shared decision-making process can shift some of the emotion-laden responsibility to forego additional medical interventions away from the patient and thereby make patients feel more comfortable with end-of-life decisions, as Dr. Haveford has done in this case.

Disagreements about Patient Care

How should Isalita, as a medical student, handle her sense that Dr. Haveford is not honoring Janet's wishes? In *The Anatomy of Hope*, Jerome Groopman tells the story of a patient who refused breast cancer treatment against the recommendation of the attending physician [14]. Although she did not tell the attending physician her rationale, she confided in Dr. Groopman, then a resident, who shared her religious faith, that she was refusing treatment because she believed her illness was a "punishment from God" and that she must accept her fate. Since medical students might spend more time with patients, they can sometimes have additional insight into a patient's values. In such a case, medical trainees should draw upon their primary roles as learners, ask questions of attending physicians, and express their concerns to faculty teachers and mentors, one of whom in this case is Dr. Haveford.

Given their place in the medical hierarchy, it can be difficult for many medical students to confront superiors, particularly when disagreements arise. However, a major tenet of practice-based learning is the need to recognize that the supremacy of the patient's best interest will always supersede seniority or position. While imposed power dynamics are real and mentors might occasionally be dismissive, students are obligated to advocate for their patients. As such, medical students, along with any member of the care team, are entitled and entrusted to be respectful but outspoken in articulating concerns about patient care, which includes having the moral courage to supersede traditional hierarchies when necessary [15]. Much responsibility also lies with the medical institution to foster an environment where honest dialogues can occur without fear of repercussion. In most cases, including this one, such a statement from Isalita will engender a discussion with Dr. Haveford, which may or may not affect his decision in this case, but that will undoubtedly further Isalita's understanding of what it truly means to be entrusted with a patient's life.

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