

AMA Journal of Ethics

March 2015, Volume 17, Number 3: 209-214

ETHICS CASE

Withholding Information from an Anxiety-Prone Patient?

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Ms. Chen is in general good health. The only medication she takes is duloxetine, a serotonin/norepinephrine reuptake inhibitor that her psychiatrist prescribed for generalized anxiety disorder. After experiencing increased pain for three months when straining and lifting objects, Ms. Chen made an appointment with her primary care physician, who took a history, examined Ms. Chen, and referred her to a general surgeon for further evaluation. The surgeon performed a physical exam and diagnostic workup that confirmed that Ms. Chen had an inguinal hernia and scheduled her for elective hernia repair the following week.

On the morning of the scheduled operation, Ms. Chen was greeted by Dr. Billings, a third-year resident in anesthesiology. The surgeon had informed Ms. Chen about the risks of the surgical procedure and had obtained her informed consent. But the nurse told Dr. Billings that Ms. Chen was “very worried about dying” and “barely made it through the surgery consent.” On interviewing her, Dr. Billings noted that she was a highly anxious woman who was unable to remain still. After speaking with Ms. Chen, Dr. Billings reviewed her medical history and medications and confirmed that she was a good candidate for general anesthesia.

Given Ms. Chen’s good health, low risk of adverse effects from general anesthetic, and current level of anxiety, Dr. Billings considered whether to inform Ms. Chen fully about all possible risks associated with general anesthesia, including the risk of death. She recalled an ethics grand rounds lecture in which an anesthesiologist invoked therapeutic privilege when choosing not to disclose full risk information to a psychiatric patient. Dr. Billings stepped out of the holding area to gather her thoughts. Unable to locate the attending physician, she considered whether withholding the risks of anesthesia from Ms. Chen would be a failure to obtain truly informed consent.

Commentary

The case of Ms. Chen and Dr. Billings is not rare. Anxiety is common in the preoperative period, with an estimated incidence of up to 80 percent [1]. With anxiety disorders and, more specifically, generalized anxiety disorder, affecting roughly 15 percent and 2-3 percent of the US population respectively [2, 3], preoperative situational anxiety is often superimposed upon an existing anxiety disorder. Although some degree of anxiety is considered to be a normal response in the preoperative period, it has been shown to have deleterious consequences for the postoperative course, including increased postoperative pain and infection risk, decreased wound healing, and long-term cognitive or behavioral changes [4-8].

As anesthesiologists, we see it as our responsibility to help mitigate this anxiety response as part of a comprehensive perioperative care plan. Our preoperative interaction, which includes a history and physical examination as well as the informed consent process, has the potential to greatly assuage anxiety through the establishment of a therapeutic relationship and the correction of informational asymmetries. This is not the case, however, for all patients. We need to appreciate the nuances of informed consent and therapeutic privilege before we can decide whether it is appropriate for Dr. Billings to limit informed consent and invoke therapeutic privilege.

Informed consent, as we know it today, developed as a legal construct through a series of court cases that spanned the twentieth century. The courts' decisions upheld a patient's right to self-determination and found that operations performed without assent, initially, and then without consent, subsequently, were battery [9, 10]. By assenting, a patient agreed to proceed with a procedure without being sufficiently informed of specific risks and benefits to give consent. Interestingly, these decisions and the ethical principles they upheld were at odds with the codified beneficence-based medical ethics of the time. As the practice of medicine became more participatory and patient-centered, physicians increasingly recognized that the informed consent process was integral to patient care.

At present, it is generally accepted that informed consent should be obtained from all patients with decision-making capacity undergoing any procedure more invasive than, for example, a lab draw or basic physical exam, provided that the situation is not so urgent that doing so would delay emergency treatment and cause harm. Patients show evidence of decision-making capacity by (a) being able to understand medical problems, proposed treatments, alternatives, options to refuse treatment, and foreseeable consequences of accepting or refusing proposed treatments and (b) being able to express a rational, internally consistent preference [11]. Decision-making capacity is different than competency, which is usually determined in a binary fashion (being competent or not being competent) by a court [11].

The informed consent discussion should include four components: (1) the facts of the patient's situation or condition, (2) the potential treatment options including no treatment, (3) the risks and benefits of the proposed treatment and nontreatment options, and (4) the physician's recommended course of action. The quantity and specificity of the information provided should be tailored to the preferences, needs, and understanding of the patient. Patients may refuse part or all of the information provided or may designate another person to participate in the care discussion on their behalf.

Although it is exceedingly controversial, some argue that, under very special circumstances, the physician may invoke therapeutic privilege and withhold information regarding a diagnosis or treatment *if disclosing it would pose a serious threat to the patient* [12]. The rationale is that, in such cases, the principles of beneficence (the physician should act in the best interest of the patient) and nonmaleficence (the physician should not harm the patient) supersede the principle of respect for patient autonomy.

Dr. Billings was correct to step back to collect her thoughts and to seek out her attending physician for advice regarding how best to manage the informed consent process for her

highly anxious patient. This is a good practice whenever faced with an unexpected hitch. She will need to consider a number of things before she can make a reasoned judgment about whether to proceed with the usual informed consent process or to invoke therapeutic privilege. First, she must decide whether Ms. Chen is in a reasonable mental and emotional state to provide informed consent. Second, she must determine the quantity and depth of information needed and wanted by Ms. Chen. Third, based on these things, she must assess the potential for immediate and serious harm to Ms. Chen that could result from the informed consent process. Considering these things separately creates a framework for Dr. Billings's decision-making process.

Is Ms. Chen in a Position to Give Informed Consent?

It is a matter of some debate whether anxiety or pain in the preoperative period creates sufficient duress to render a patient unable to fully participate in the informed consent process. A similar situation occurs with women who are in labor [13]. Provided that a patient is not under duress from lack of pain medication or alternative treatments and that she is not so distressed as to render her unable to understand the choices, communicate her concerns, or make decisions regarding her care, her consent can be obtained. In some cases, patients may be able to participate after receiving anti-anxiety medication if they retain decision-making capacity.

Prior to her arrival in the preoperative holding area, there is no question that Ms. Chen would have been considered to have decision-making capacity and would have been expected to participate actively in the informed consent process. Following her consent to surgery, however, her demeanor changed, and she became highly anxious and unable to sit still. Without engaging Ms. Chen further, Dr. Billings has no way of knowing whether she is able or willing to consent for herself. Often, it is not until patients are participating in the informed consent process that it becomes clear that they are not in a position to do so.

How Much Information Should Ms. Chen's Consent for Anesthesia Entail?

According to the most recently published AMA Code of Medical Ethics' opinion on informed consent [14], the quantity and specificity of the information provided should be tailored to the preferences, needs, and understanding of the patient. There is no specific distinction made between high- and low-risk patients, high- and low-risk procedures, or minor or major complications. Legally, in order to conform to the "reasonable patient" standard that is upheld in most states, the patient should be provided with all the information that a reasonable patient would consider material to making a decision. Information that is already known to a patient or is considered general knowledge does not necessarily need to be discussed. And the patient may choose not to be told some or all of the information.

If Ms. Chen is able to participate in the informed consent process, Dr. Billings should discuss her anesthetic options given her past medical history, planned surgery, and mental state. Included in this discussion should be the frequently occurring risks and benefits of these options as well as Dr. Billings's recommended anesthetic choice (i.e., general or local). The sharing of information should be a back-and-forth exchange between the patient and physician and not merely a listing of every possible risk and benefit. Given Ms. Chen's good health and the nonelevated risk of the proposed procedure, Dr. Billings should let Ms. Chen dictate how much information she wants about the more rare or serious risks. If she

explicitly states that she does not want to be told about the risk of death or other serious complications, Dr. Billings should respect that wish and not force the information upon her. It is important to remember that the back-and-forth exchange can be as informative for the clinician as it is for the patient. For example, general anesthesia was most likely chosen for Ms. Chen based on her preoperative diagnosis of anxiety, but, if in the course of the informed consent discussion, Ms. Chen clarifies that her fear of perioperative death is really a fear of not waking up from general anesthesia, a regional anesthetic may be her preference. Without the informed consent process, Ms. Chen may not have known about the availability of a regional anesthetic, and Dr. Billings may not have considered it to be an option for this particularly anxious patient.

Could Informed Consent Harm Ms. Chen?

Multiple studies that have attempted to determine and quantify the anxiety-generating effect of informed consent provide mixed results about whether a more detailed consent process is physiologically or psychologically harmful to a patient [15-19]. Conflicting results aside, these studies may not be applicable to any specific patient. Therefore, the first question that Dr. Billings should consider is whether the informed consent process itself will directly harm Ms. Chen. A mild increase in anxiety prior to surgery is both somewhat expected and generally acceptable, but could an extreme reaction lead to a myocardial infarction, hypertensive emergency, or active suicidal ideation? A more subtle question is whether the increased anxiety that the consent process entails could lead to a poorer surgical outcome. In the latter situation, it would be difficult to justify violating a patient's autonomy by withholding information that the patient has not given the physician permission to withhold. It is because of the first question—whether the increase in anxiety could lead to physical or psychological crisis—that the concept of therapeutic privilege exists.

Therapeutic privilege or exception is a concept that justifies withholding information regarding a diagnosis or treatment from a patient if the disclosure of that information could lead to direct harm to the patient. It is not a means to allow physicians to withhold information that may cause a patient to forgo a treatment course that a physician deems beneficial or even necessary (i.e., bypassing respect for patient autonomy in the name of beneficence). Neither is it a means to allow a physician to forgo a potentially uncomfortable discussion if the risks of a poor outcome are perceived to be low. The AMA Code of Medical Ethics' opinion on withholding information from patients [20] considers doing so without patients' knowledge or consent ethically unacceptable. It recommends that all attempts should be made to tailor the disclosure of information to meet the needs and preferences of the patient. The code does make allowances for partial or delayed disclosure provided that a plan is in place to prevent a permanent delay. Since Ms. Chen is otherwise healthy and not experiencing active suicidal ideation (the direct harm of concern in this case), invoking therapeutic privilege would not be an ethically sound decision in this situation. Every attempt should be made to uphold and foster Ms. Chen's autonomy unless it is clearly dangerous to do so.

Conclusion

In summary, after she considers these questions, Dr. Billings should make every attempt to engage Ms. Chen in the informed consent process. The depth and breadth of

information provided to Ms. Chen will depend on her preferences, needs, and ability to understand information given her current mental state. It may be that Ms. Chen will refuse part or all of the information that Dr. Billings offers to provide or that she will choose to designate a proxy to consent for her. In both of these cases, Dr. Billings should comply with Ms. Chen's wishes and feel confident that this does not represent a failure to obtain truly informed consent. There is also the possibility that Ms. Chen's anxiety will be partially assuaged by the knowledge of the low risk of death from general anesthesia or that the discussion will lead to an anesthetic plan that is more acceptable to her. In both of these cases, invoking therapeutic privilege would not only deprive Ms. Chen of her autonomy but also cut off an opportunity to provide her with the best care possible. If at any point during their interaction Dr. Billings thinks Ms. Chen's decision-making capacity is dwindling, it may be more ethically sound to cancel the nonurgent procedure, make provisions for Ms. Chen's safety, and reschedule for a later time rather than to invoke therapeutic privilege and move forward as planned.

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ISSN 2376-6980