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Abandon Informed Consent in Favor of Probability-Based, Shared Decision-Making Following the Wishes of a Reasonable Person

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Abstract

Legally and ethically physicians must provide information to patients so they may make an informed decision about invasive procedures. The problem is who decides what information to provide. Is it the reasonable patient or the reasonable physician? Individual patients and individual physicians may differ from the norm on what is reasonable. This problem may be solved by shared decision-making in which the preferences of the patient and the probability-based knowledge of the physician are used to co-produce an optimal choice. Currently, patients are seldom prepared to engage in shared decision-making, and vestiges of meaningless "informed consent" are common. The present case study illustrates how "reasonable person" survey data may be used by a patient to engage in probability-based, shared decision-making with a surgeon planning to perform a laminectomy. Recommendations include probability-based, shared decision-making training for patients and physicians and improved documentation to facilitate learning.

Keywords

shared decision-making, informed consent, reasonable patient, probability of harm

Introduction

This case report underscores the widespread problem of patients not receiving the timely information they need to make a wise decision about their medical care. A landmark legal decision in 1957 established that a physician must provide sufficient information to a patient so he may make an informed decision. The physician involved had not explained to the patient that one of the possible outcomes of his translumbar aortography could be paralysis. The patient was paralyzed after the procedure, and a California Court of Appeals found the physician liable for not disclosing this possibility (1). The difficult question becomes who decides what information should be revealed by the physician to his patient when an invasive procedure is a possibility. States are almost evenly divided on whether that should be what a reasonable person wishes to know or what a reasonable physician thinks should be disclosed (2). The basic problem is that the preferences of reasonable people vary, and physicians are often going to disagree on what is reasonable to disclose and how to express the probability of risks.

To manage this ethical dilemma, the concept of shared decision-making (SDM) was developed to form the basis of patient-centered care through a respectful dialog in which the preferences of the individual patient and the knowledge of the individual physician interact to make an optimal decision. Tools have been developed to measure SDM through patient reports (3). In addition, a tool has recently been developed to assess documentation of informed consent. When that tool was applied to documentation in 25 hospitals, the results were astonishing. Of the 20 possible points that define quality informed consent, the average hospital score was <5 points (4). The measurement tool checked for documentation of procedure description, how it will be performed, rationale for the procedure, benefits of the procedure, alternatives to the procedure, and timeliness of delivering information to the patient.

Only recently has research been conducted to ascertain variations in patient preferences when it comes to the

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information that they wish to have during an SDM process with their physician. The hypothetical research setting was a teaching hospital in which a patient faced the possibility of an invasive procedure. A national survey using a 10-point questionnaire found that the majority of participants definitely wanted to know far more than is generally disclosed to the patient (Table 1) (5). The results of this study have been translated into legal strategies to ensure that patients are appropriately involved in SDM as part of informed consent (6). The present author had an opportunity to apply the results of the national survey to engage his surgeon in SDM and later compare the SDM to the standard informed-consent information provided by the hospital where his laminectomy was to be performed. The present case study illustrates the chasm between patient-centered SDM and informed consent.

Description of the Case

The patient was a 76-year-old, overweight male with no health issues beyond chronic back pain. After 12 weeks of physical therapy had produced limited success in relieving his pain, his primary care physician recommended an X-ray, magnetic resonance imaging (MRI), and follow-up visit with a neurosurgeon. The patient and surgeon participated in an unhurried SDM session based on the patient's preferences for information and outcomes. A month later, immediately before the surgery, the patient was asked to initial a document in which "Risks and Hazards" were disclosed.

Results

Below is a summary of the 9 steps involved in the SDM process between patient and surgeon a month before surgery at a Houston hospital system recognized for excellence.

Options

The patient's preferences were for a solution that did not require pain medications or periodic injections. Given that he had tried physical therapy with limited success and his MRI showed constriction of his spinal column at L3–L4, L4–L5, and L5–S1, the solution seemed clear that surgery was the best option. Dr Thomas (not his real name) said that the probability of a serious problem from minimally invasive laminectomy, which he had proposed, was no more than 1%, and of this, about 0.4% involves surgical site infection, which can be managed by antibiotics. When asked about the planned use of devices, he said that the old way involved devices, but the minimally invasive method he uses would not involve any devices left behind in the patient's body. He cautioned that the surgery would not deal with mild arthritis evident in the MRI.

Drugs

Given the patient's history of no adverse reactions to anesthesia, there was a minimal risk from a reaction to anesthesia, but the risk is not zero.

Decision Aids

These were unnecessary given the patient's preferences and the explanations given by Dr. Thomas as he showed images of the MRI and the spinal constrictions noted above.

Who Will do Surgery?

Dr Thomas said that he alone would do the patient's surgery. He used to work at a Baltimore teaching hospital where residents were common, but he prefers doing surgery himself.

Table 1. Percentage of Responders to a National Survey (n = 1067) and a Survey of the HPESS Community (n = 63) That 'Definitely' Wanted to Have an Answer to the Question Posed in a Hypothetical Situation Where an Invasive Procedure may be Necessary While Hospitalized. Choices for Desiring Answers to Questions Were as Follows: Definitely not (1), Probably not (2), Neutral (3), Probably yes (4), and Definitely yes (5).

Shortened survey template of 5-point responses to questions[a]	National survey (%)	HPESS survey[b] (%)
I want to know all my treatment choices (including doing nothing) and the benefits and risks of each one.	75	95
I want to know the risks if any drugs given to me will be off-label or have a box warning.[c]	72	73
I want access to decision aids if available.	61	70
I want to know who will do my invasive procedure.	68	84
I want to know my out-of-pocket cost.	69	68
I want a trusted person to be present during SDM.	54	62
I want to be able to make entries in my medical record.	38	48
I want to review informed consent documents at least one day in advance.	47	52
I want to know what to expect during recovery, including the risk of infection.	76	90

[a]Patient wishes are shortened versions from the original study (Reference #5). Terms such as "off label," "box warning," and "decision aid" were defined prior to applicable survey questions.
[b]Health Professions Educators Summer Symposium (HPESS) consists of leaders in medical, nursing, and health-administration education.
[c]This statement combines two questions from the original survey.

Costs

The patient asked if there was a chance Medicare would not pay for his surgery. Dr Thomas said, "Medicare will have no trouble approving your surgery when they see your MRI results."

Trusted Person Present

The patient's wife was present to help him think about his preferences and ask appropriate questions.

Documentation

The *patient* placed a summary of the SDM process in his medical record after the SDM session. There was no other record of the SDM present in his medical record. The SDM was conducted with Dr Thomas over a period of 50 min on August 20, 2021.

Timing of Information

The SDM discussion was a month prior to the surgery.

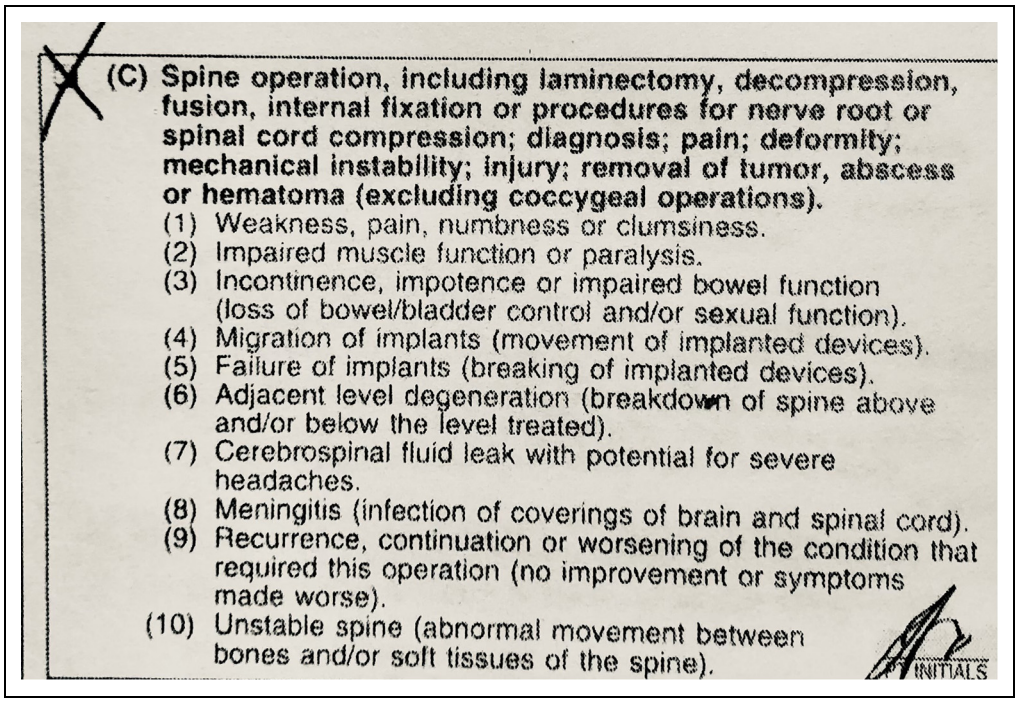
Expected Outcomes after Surgery

Dr Thomas said that the patient should be able to walk out after the outpatient procedure. He may experience some discomfort for a few days as some swelling and inflammation develop during the healing process. The patient was advised not to swim for 1 month to control the risk of infection, and he must not lift more than 20 pounds.

One month after SDM, it was time for surgery. In the hour before that procedure, the patient was given forms to sign, including a lengthy set of boxes called "RISKS AND HAZARDS." He was asked to initial the panel pertaining to laminectomy as shown in Figure 1. If he had not had the SDM session with Dr Thomas, he would have stopped the surgical preparations. The panel contained no useful information for the patient to make an informed decision. There was no link between the procedures and potential bad outcomes. No probability information was disclosed. Ultimately, the outcomes discussed during SDM were as anticipated except for a superficial bruise and hematoma that formed in the patient's lower back a few days after surgery. It spread over an area of approximately 300 cm^2. A call to the surgeon and texting him a photograph of the area led to his reassurance to the patient that this was of no concern. As the surgeon predicted, it gradually disappeared over the next few weeks. The patient never needed prescription pain medications and was soon engaged in the physical activities he enjoys with less pain than before surgery. He still experiences back discomfort at times, perhaps because of his mild arthritis.

Lessons Learned

- Informed consent may be improved by the application of the principles of SDM including quantification of the probabilities of adverse outcomes when known. In many cases, those probabilities may be uncertain. Some examples where probabilities are known include the following: risk of going to the


(C) **Spine operation, including laminectomy, decompression, fusion, internal fixation or procedures for nerve root or spinal cord compression; diagnosis; pain; deformity; mechanical instability; injury; removal of tumor, abscess or hematoma (excluding coccygeal operations).**

(1) Weakness, pain, numbness or clumsiness.
(2) Impaired muscle function or paralysis.
(3) Incontinence, impotence or impaired bowel function (loss of bowel/bladder control and/or sexual function).
(4) Migration of implants (movement of implanted devices).
(5) Failure of implants (breaking of implanted devices).
(6) Adjacent level degeneration (breakdown of spine above and/or below the level treated).
(7) Cerebrospinal fluid leak with potential for severe headaches.
(8) Meningitis (infection of coverings of brain and spinal cord).
(9) Recurrence, continuation or worsening of the condition that required this operation (no improvement or symptoms made worse).
(10) Unstable spine (abnormal movement between bones and/or soft tissues of the spine).

INITIALS

Figure 1. Panel provided to the patient within an hour of laminectomy surgery.

emergency department with complications within 30 days after coronary artery bypass surgery (7), probability of tendon rupture after taking a fluoroquinolone drug (black box warning) (8), and a 10-year probability of leukemia or brain cancer in children given computed tomography scans (9).

- Risks and hazards must be specific to the planned procedure and contain a *probability* of serious adverse outcomes, individually or collectively, when known. For example, it is worthless to the patient to declare that "paralysis" is a risk without declaring its probability. The 1% "collective" probability limit to serious complications presented during SDM by Dr Thomas was reassuring to the patient in this case study.
- Consent information and documents should be presented to the patient long before surgery. Patient decision aids should include probabilities of benefit and harm when known.
- The Centers for Medicare and Medicaid Services (CMS) has begun to require SDM before a few procedures, but widespread use in practice has proven challenging (10). The CMS must require documentation of SDM. Physicians must be trained and paid for the time spent on SDM.
- The CMS should develop an SDM template based on the wishes of most patients. Table 1 offers a starting point.
- The CMS should implement a program to educate all beneficiaries on how to engage their physicians when an invasive procedure is contemplated. This training should include a tutorial on probabilities of benefits and harms, and how the patient may document SDM in their electronic health record.
- The strength of this case report is that it originates from a patient's experience in a large healthcare system where back surgeries are common. The "informed consent" panel shown in Figure 1 is clearly used for a variety of spine operations. The SDM process will vary with the patient's need for answers and the surgeon's available time. To our knowledge, no one has compared an SDM process based on the wishes of a reasonable patient (Table 1) to the generic informed consent panel offered by a major healthcare system. As a case report, the study has the limitation that it represents a single patient's experience that should be generalized with caution.

Conclusions

Genuine informed consent is best accomplished by formal, timely, and probability-based SDM. Presently, this is seldom done, leading to dissatisfied patients, harm to patients, and overuse of procedures. This case study illustrates how patients may benefit from probability-based SDM as opposed to "canned" informed consent documents.

Declaration of Conflicting Interests

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Ethics Approval

Informed consent for patient information to be published in this article was not obtained because the author is the patient whose case is described in the article.

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