(4) an injury for which monetary compensation is adequate relief.[18]

A TYPICAL MEDICAL INFORMED CONSENT CASE

A typical medical informed consent case usually arises in conjunction with an underlying medical procedure. For example, if a patient suffers a stroke during an invasive vascular procedure, the patient might allege—in addition to and separate from any medical malpractice claim—that, because the physician did not discuss the risks and benefits of the procedure and reasonable alternatives to it, the patient could not make an informed decision whether to proceed. As previously noted, to establish a lack of informed consent case, a patient must first show that the physician had a duty to discuss the risks and benefits of the procedure and reasonable alternatives to it with the patient, and that discussion should have been in accordance with an accepted standard within the medical community.[17] That is, the physician is expected only to disclose risks that might reasonably be known to occur with the particular procedure. Therefore, the discussion might vary depending on the nature of the procedure and the patient's relevant comorbidities. States have applied different approaches in articulating the standard regarding the physician's duty to disclose.

DEFINING THE STANDARD OF DISCLOSURE

Two dominant approaches, the "professional" standard and the "materiality" standard, define the standard of disclosure of information by which a physician's duty to the patient is measured.[19] The professional standard requires the physician to disclose information that other physicians possessing the same skills and practicing in the same or a similar community disclose in a similar situation.[20] The second approach by courts is the materiality or "prudent patient" approach, allowing the jury to decide whether other information would have been considered important by a reasonable patient in making a decision and therefore requiring disclosure.[21]

The courts recognize situations when a physician's nondisclosure will be excused, including cases of the patient's mental incompetence, medical emergencies, and the therapeutic privilege exception.[22] If a patient is incompetent to make a reasoned decision, then disclosure to the patient might not be required.[23] The physician can also withhold information under the therapeutic privilege if disclosure would interfere with treatment or would adversely affect the condition or recovery of the patient.[24] The emergency exception to disclosure applies in situations where attempting to secure consent would delay necessary and proper treatment.[25] Last, physicians need not disclose risks of which the patient is already aware or risks that are commonly known.[26] Individual state law and court decisions determine which approaches and exceptions apply in an individual physician's practice.

PHYSICIAN'S DUTY TO DISCLOSE RISK INFORMATION

Materiality jurisdiction courts have attempted to provide some guidance for physicians by suggesting that the physician's duty to disclose risk increases as the magnitude of the risk increases. These courts uniformly fail to give explicit guidelines or to identify on what scale risks are to be measured.[27] All severe risks (death, paralysis, loss of cognition, loss of a limb) should always be disclosed, even if the probability of occurrence is negligible. Further, even less severe risks, if frequent, should always be disclosed. Nominal risks with low probability of occurrence need not be disclosed. Courts do not place emphasis solely on consequences, recognizing frequency as an important component of risk.[28] The professional standard asserts the doctor's duty to disclose is what a reasonably prudent physician with the same background, training, and experience would have disclosed to the patient in the same or similar circumstances. The professional standard does not give explicit guidelines regarding the disclosure of risks.

The courts stress that full disclosure is not required. Full disclosure is a slippery slope for physicians involved in medical informed consent. There are reasons full disclosure as a standard of practice should not be expected. First, the number of risks possible from even a routine procedure is large, and potential risks can span a range of consequences. For example, in a footnote, the California Supreme Court listed some of the risks of having blood drawn: "[T]he risks…are said to include hematoma, dermatitis, cellulitis, abscess, osteomyelitis, and death, to mention a few."[29] Second, the burden of identifying small consequences in extremely unlikely risks is too great a burden on the physician, and the resulting choice by the patient will be impaired by a litany of consequences. Despite the courts' pronouncements that full disclosure is not required, they have failed to delineate any clear limits on what must be disclosed. The California Supreme Court articulated this uncertainty: "One cannot know with certainty which medical consent is valid until a lawsuit is filed and resolved."[30] There does not appear to be a standard of disclosure to which physicians can adhere to avoid liability with certitude.

DOCTRINE OF MEDICAL INFORMED CONSENT

The doctrine of medical informed consent states that, before a patient elects to proceed with a treatment that has

risk, there must be a balanced discussion of the treatment strategy, including the potential risks and hoped-for benefits. The magnitude of the risks and their frequency should receive special emphasis. Also considered are alternative treatments and their benefits, risks, and measured utility; the likely results of no treatment; and the probability of a good outcome with the proposed strategy. A good outcome and the major anticipated problems during recovery are described as well as the estimated time to resume normal life activities. This information must be presented in language the patient can understand, and treatment should not proceed until the physician believes the patient understands the risks and benefits and decides to proceed on the foundation of that understanding.[31]

The legal foundation for adopting the doctrine of medical informed consent is 2-fold: (1) to establish and promote patient autonomy and (2) to promote informed, rational decisions. The courts hold that it is reasonable to require physicians to inform, educate, and partner with patients because patients are generally unable to dissect the details of medical science needed to make an educated decision about treatment.[29] This educational process should inform the patient enough to allow for an informed decision. Information disclosure will not necessarily lead to an ideal patient-physician partnership, but it should promote patient autonomy in the decision-making process and achieve a foundation for an ethical and trusting relationship between a physician and patient.

To give valid informed consent, the patient must be competent and the patient's actions must be voluntary. *Voluntary* means "of free mind and free will." The patient must not be cognitively impaired by medication, personal emotional stress, or external stress by family members or physicians. For example, one case involved a patient who was given a sedative to sleep and subsequently awakened in the middle of the night to give consent for a hernia operation. The court held that the medical consent was invalid because the patient was unlikely to understand what permission he had granted after being awakened from sleep and after taking a sedative.[32]

Determining incompetence and competence is a matter for the court and not a question of fact for the layperson. In medical informed consent the focus should be on the capacity of the patient. Capacity means the ability to process information received and to communicate a meaningful response. An element of capacity is that the person making the decision is an adult and has not been judged incompetent or is not otherwise prohibited by law from exercising that decision-making capacity. *Decision-making capacity* means the ability to understand the significant benefits, risks, and alternative to proposed health care and to makeand communicate a health care decision.[33]

MEDICAL CONSENT

The purpose of medical consent, through medical consent forms and through documentation of the informed consent discussion in the medical record, is to have evidence of the exact terms of the medical consent in case of future disagreement. If a patient sues a physician, an outpatient surgery center, a medical group, or a hospital and alleges lack of informed consent, the defendant will be able to present the written consent form or the documentation of the discussion in court as evidence that medical consent was in fact secured. If the medical consent form or documentation of the discussion in the medical record is comprehensive and specific in terms of risks and benefits, and if the medical consent was granted voluntarily by a competent patient who understood the information presented, the probability of a successful lawsuit is low.[34] However, the medical consent form does not equate to medical consent. Rather, it represents evidence that the medical consent process occurred. A patient could present evidence that medical informed consent did not occur, despite a signed form,[35] for example, when a nurse presented the risks to the patient and the physician signed the form as if consent had been obtained.

What should a medical consent form contain? First, a consent form is not necessary to achieve valid medically informed consent. If an entity, such as a hospital, an outpatient surgery center, or other health care organization, chooses to honor a medical informed consent form, the form should contain all the information needed to comply with the elements of medical informed consent. The form should contain an accurate description of the proposed procedure, the risks and benefits of the proposed procedure, the potential advantages and disadvantages of no treatment, alternative treatment strategies and their risks and benefits, the potential for a successful outcome, the estimated recuperation time, and the estimated time required to return to normal activity. The consent form should contain the name of the physician involved and clauses dealing with photography, disposition, and use of removed tissues, organs, and body parts. Patients should be made aware that they are allowed to strike out any part of the medical consent form with which they do not agree or to which they do not consent. If a patient does not understand details of the treatment, the patient and physician should discuss treatment and risks to reach mutual understanding.

If a physician believes the limits placed on the medical informed consent hamper standard medical practice, he or she should document all the patient-imposed restrictions in the record, with a discussion of how the limits placed on the physician limit his or her ability to proceed in a standard fashion, and that the limits were described to the patient.

Alternatively, if a physician believes the restrictions seriously inhibit good medical practice and might lead to a suboptimal clinical outcome, he or she may advise the patient to seek care with another physician.

WITHDRAWING CONSENT OR REFUSING TREATMENT

May a patient withdraw consent after signing a medical consent form? Consent must be freely given and can be freely withdrawn at any time. Whether consent was given orally or in writing does not affect the patient's ability to change or withdraw consent. Physicians may choose to allow 24 to 48 hours for patients to reflect after consent to a treatment strategy. During this time, patients can weigh the alternatives and come to an independent conclusion either to proceed with or to withdraw from the proposed treatment. A time for patients to appraise the risks and benefits reinforces the validity of medical informed consent. If a patient orally indicates a desire to withdraw medical consent, the physician would be wise to execute a withdrawal of consent form, noting time of day and date consent was withdrawn, or to carefully document in the medical record the details of consent withdrawal including a time and date.

May a patient refuse treatment? A competent patient may decline any and all treatment. Even mentally ill patients are generally considered competent to refuse treatment. Physicians would be prudent to have a patient who has been diagnosed with mental illness and who refuses an apparently beneficial treatment evaluated by a psychiatrist. In some situations, patients can be compelled to receive treatment.[36] For example, a mentally ill patient could be considered a danger to society and institutionalized against his or her will.[37] Competent individuals with contagious diseases may refuse treatment, but public health officials may quarantine or involuntarily hospitalize and isolate them if they are dangerous to other people.[37] This policy is based on broad "police power" that states have (and can exercise through their departments of health) to protect the health and safety of the public. The reason for refusal of treatment can be rational or irrational. Whether rational or irrational, decisions are legally binding on the physician and the hospital. Individual freedom is guaranteed only if people are given the right to make choices that would generally be regarded as irrational behavior.[38] Some states also require hospitals to ensure proper consent is obtained for no treatment. This consent for no treatment should contain a release of medical responsibility and any associated liability for the hospital, nurses, and employees, together with all physicians connected in any way to the patient.[39]

GOOD CLINICAL PRACTICE AND INFORMED CONSENT

Are good clinical practice and informed consent inseparable? Respect for patient autonomy in clinical practice is of great moral importance in our society. The moral and legal responsibility of medical informed consent depends on the transmission of appropriate information to patients. We believe patients' choices must not be coerced by members of the health care team or by other third parties, such as friends, family, or payers. Equally, we believe patients must be competent to consent; they must understand, remember, consider, and believe clinical information given to them about the specific treatments. The moral foundation for the requirement of medical informed consent in general is not disputed. The question arises whether in certain situations exceptions from the general requirement of medical informed consent would be acceptable. An exception to medical informed consent could be motivated by the idea that an exception is reasonable if insistence on the requirement of medical informed consent causes more harm than good.

INFORMED CONSENT IN EMERGENCIES

Is medical informed consent always necessary in emergency medical situations? Is a patient who is having an acute myocardial infarction sufficiently competent to understand what he or she is being told? In a survey of Swedish cardiologists about their perceptions of medical informed consent during acute myocardial infarction, 86% thought that patients were unable to comprehend all the information provided and so, by definition, were unable to give fully informed consent.[40]

What evidence is there that patients with acute illnesses themselves fail to understand all the issues in the medical informed consent process? A report from the Fourth International Study of Infarct Survival revealed that only 31% of 129 patients perceived that they had full comprehension of the trial, and 19% thought they did not understand the trial.[41] A review of patients with subarachnoid hemorrhage revealed only 19% of those who had given medical informed consent themselves could remember the consent process.[42] The studies suggest that during a medical emergency many of the patients were too ill to give fully informed consent. Does this mean that patients with an acute myocardial infarction or subarachnoid hemorrhage are unable to engage in the decision-making process of medical informed consent? The answer is no. Although acute myocardial infarction is a medical emergency and there is evidence that some patients do not fully comprehend all the information to make a fully informed decision, some patients do comprehend and are capable of doing so. A dia-

TABLE 3. **Ideal Statute Outlining Physicians' Duty to Disclose**

Information shall be supplied to the patient or the patient's guardian or legal surrogate before obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure as follows
Describe condition to be treated
Describe proposed treatment or procedure
Outline intended and anticipated results of proposed treatment or procedure
Describe recognized alternative treatments or procedures, including the option of not using these treatments or procedures
Describe recognized material risks of serious complications or mortality associated with the following
Proposed treatment or procedure
Recognized alternative treatments or procedures
No treatment or procedure
Outline recognized benefits of alternative treatments or procedures and risks of alternative treatments
Disclosure of information and consent provided for in this statute shall not be required in certain conditions
Emergencies as defined by statute
When surgical or diagnostic procedure is generally recognized by reasonably prudent physicians not to involve a material risk to the patient
When the patient, another person, or people authorized to give consent pursuant to this chapter make a request in writing that the information provided for in this Code section not be disclosed
When prior consent has been obtained within 30 days of the surgical or diagnostic procedure as a part of a course of treatment for the patient's condition, complying with the requirements of this statute for the surgical or diagnostic procedure; provided, however, that if such consent is obtained in conjunction with the patient's admission to a hospital for the performance of such procedure, the consent shall be valid for 30 days from the date of admission or for the period the person is confined in the hospital for that purpose, whichever is greater
When the surgical or diagnostic procedure is unforeseen or is not known to be needed at the time consent is obtained, and the patient has consented to allow the responsible physician to make the decision concerning such procedure

logue between the physician and patient is essential. This is a unique opportunity to involve appropriate family members or health care surrogates in decision making during emergencies. Patients do not need to stand alone in the patient-physician partnership.

THE PARADOX OF CHOICE

Responsibility for medical care has landed on the shoulders of patients with a resounding thud. Patients have the choice of telling physicians what to do in relation to health care decisions. The tone of medical practice has shifted from paternalistic to consultative, in which the physician lays the possibilities before the patient, with the potential pluses and minuses of each, and the patient makes a choice. This attitude has been well described by Atul Gawande: "Only a decade ago, doctors made the decisions, patients did what they were told. Doctors did not consult patients about their desires and priorities…. They were regarded as children: too fragile and simple minded to handle the truth, let alone make decisions."[43] According to Gawande, *The Silent World of Doctor and Patient*, by physician and ethicist Jay Katz, launched us into the era of autonomous patient choice. There is little doubt that this change in the decision-making paradigm has improved the quality of medical care generally. Yet no single paradigm fits all patients. Gawande suggests the shift in responsibility has gone too far: "The new orthodoxy about patient autonomy has a hard time acknowledging an awkward truth: patients frequently don't want the freedom that we've given them. That is, they're glad to have their autonomy respected, but the exercise of that autonomy means choosing sometimes to relinquish it."[43] Gawande describes a family medical emergency where his newborn daughter stopped breathing, and the family rushed her to the emergency department. The physicians on duty asked Gawande if he wanted his daughter intubated. He said that he wanted the physicians to make that decision for him: the uncertainties were savage, and he did not want to bear the responsibility of making the wrong call.[43] Gawande did not want to have to live with the guilt of making the wrong call.

When it comes to medical treatment, patients see choice as a burden and a blessing. Physicians must evaluate each patient-physician relationship individually and identify the level of responsibility each party wants to assume in the decision-making process. This process must be documented in the medical record and must detail the assumed responsibilities of each partner in the patient-physician relationship. The art of medicine demands an ability to apply multiple paradigms to the decision-making process when guiding patients through complex medical decisions. This process requires empathy, time, mutual understanding, and courage.

CONCLUSION

Medical informed consent is essential to a true patient-physician relationship. Patients need to participate in the informed consent process to understand the risk-benefit relationship for the proposed treatment strategy; this understanding is essential because patients are often psychologically regressed secondary to the realization that they are confronting a life-preserving procedure. Physicians need to participate in the informed consent process to provide patients with the best treatment available by sharing decision making and limiting any potential for liability. Medical ethics, common law, and, in many states, codified statutory law (Table 3) mandate the informed consent process. Physicians would be prudent to be knowledgeable in these areas of medical ethics, common law, and statutory law. Physicians would be prudent also to understand that the consent process is vital to the physician-patient relation-

ship and that no single paradigm can define the ethical, medical, and legal approach a physician should undertake to achieve informed consent. The process should be individualized within the boundaries of the patient's desires for autonomy, thus reflecting true patient autonomy.

REFERENCES

1. *Schloendorff v the Society of the New York Hospital,* 211 NY 125 105 NE 92 1914 LEXIS 1028 (1914).
2. *Grable & Sons Metal Products v Darue Engineering & Manufacturing* 125 S Ct 2363 2370 (2005).
3. Merz JF, Fischhoff B. Informed consent does not mean rational consent: cognitive limitations on decision-making. *J Leg Med*. 1990;11(3):321-350.
4. Morgan MG. Probing the question of technology-induced risk. *IEEE Spectrum*. 1981;18(11):58-64.
5. Kahneman D, Slovic P, Tversky A, eds. *Judgment Under Uncertainty: Heuristics and Biases*. Cambridge, UK: Cambridge University Press; 1982: 3350-3360.
6. *Jackson v Julian*, 694 SW 2d 434 (Tex App -Dallas 1985).
7. *Walstad v University of Minnesota Hospital,* 442 F2d 634 (8th Cir 1971).
8. *Ditto v McCurdy*, 510 F3d 1070, 1078 (9th Cir 2007).
9. *Baylor Medical University Medical Center v Biggs*, 237 SW3d 909, 922 (Tex App 2007).
10. *Hill v Medlantic Health Care Group*, 933 A 2d 314, 330 (DC App 2007).
11. *Miller-McGee v Washington Hospital Center*, 920 A2d 430, 439 (DC App 2007).
12. *Gorney v Meaney*, 150 P2d 799, 804 (Az App Div 2 2007).
13. *Kuperstein v Hoffman-Laroche, Inc*, 457 F Supp 472, 473 (SD NY 2006).
14. *Ardoin v McKay*, 939 So2d 698, 705 (La App 3d Cir 2006).
15. *Saks v Ng*, 890 A2d 983, 992-993 (NJ App 2006).
16. *Sherwood v Carter*, 805 P2d 452, 463 (Idaho 1991).
17. *Gassman v United States*, 589 F Supp 1534, 1545 (MD Fla 1984).
18. Keeton WP, Prosser WL, eds. *Prosser and Keeton on the Law of Torts*. 5th ed. St Paul, MN: West Publishing Company; 1984.
19. *Madare v Ochsner Foundation Hospital*, 505 So 2d 146 (La Ct App 1987).
20. *Canterbury v Spence*, 464 F2d 772 (CADC 1972).
21. *Cowman v Hornaday*, 329 NW 2d 422 (Iowa 1983).
22. Meisel A. The "exceptions" to the informed consent doctrine: striking a balance between competing values in medical decision making. *Wis L Rev*. 1979;1979(2):413-488.
23. *Banks v Wittenberg*, 266 NW 2d 788 82 Mich App 274 (Mich App 1978).
24. Carnerie F. Crisis and informed consent: analysis of a law-medicine malocclusion. *Am J Law Med*. 1987;12(1):55-97.
25. *Shafford v Louisiana State University*, 448 So 2d 852 (La Ct App 1984).
26. *Kissinger v Lofgren*, 836 F 2d 678 (CA 1 [Mass] 1987).
27. Maldonado JE. Strict liability and informed consent: "Don't say I didn't tell you so!" *Akron Law Rev*. 1976 Spring;9(4):609-628.
28. Stansfield MP. Malpractice: toward a viable decision standard for informed consent. *Oklahoma Law Rev*. 1979 Fall;32(4):868-890.
29. *Cobbs v Grant,* 8 Cal 3d 229 502 P2d 1 (Cal 1972).
30. *Moore v Regents of the University of California*, 51 Cal 3d D20 165 793. P 2d 479 291 Cal Rptr 147 note 41 (1990).
31. Hanson L. Informed consent and the scope of a physician's duty to disclose. *N D Law Rev*. 2001;77:71.
32. *Demers v Gerety*, 85 NM 641 515 P 2d 645 (1972).
33. Minnesota Office of the Revisor of Statutes. Decision-making capacity. Minn Stat 145C 01 subd 1b.
34. *Karp v Cooley,* 349 F Supp 827 (SD Tex 1972) aff'd 493 F2d 408 (5th Cir 1974) cert denied 419 US 845 (1974).
35. *Parikh v Cunningham,* 493 So 2d 999 11 FL L. Weekly 309 (Fla, 1986).
36. *Tarasoff v Regents of U of California*, 131 Cal Rptr 24 20 551 P2d 334 340 (1976).
37. Annas GJ. Control of tuberculosis—the law and the public's health. *N Engl J Med*. 1993;328(8):585-588.
38. Harper F, James T. The Law of Torts (1968 Supp.) sec 17.1, 61; 1968.
39. *Rogers v TJ Samson Community Hospital*, 276 F 3d 228 (6 Cir 2002).
40. Agard A, Herlitz J, Hermeren G. Obtaining informed consent from patients in the early phase of acute myocardial infarction: physicians' experiences and attitudes [letter]. *Heart*. 2004;90(2):208-210.
41. Yuval R, Halon DA, Merdler A, et al. Patient comprehension and reaction to participating in a double-blind randomized clinical trial (ISIS-4) in acute myocardial infarction. *Arch Intern Med*. 2000;160(8):1142-1146.
42. Schats R, Brilstra EH, Rinkel GJ, Algra A, Van Gijn J. Informed consent in trials for neurological emergencies: the example of subarachnoid haemorrhage. *J Neurol Neurosurg Psychiatry*. 2003;74(7):988-991.
43. Schwartz B. *The Paradox of Choice: Why More Is Less*. New York, NY: Ecco; 2004.

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May 17, 2016

The New Era of Informed Consent

Getting to a Reasonable-Patient Standard Through Shared Decision Making

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JAMA. 2016;315(19):2063-2064. doi:10.1001/jama.2016.3070

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The right of patients to be informed about care decisions in clinical practice is yet again under scrutiny, both in the United States and around the world. The well-ingrained ethical-legal process of informed consent, so fundamental to patient autonomy—or the patient's right to self-determination—was the subject of a 2015 UK Supreme Court case (*Montgomery v Lanarkshire Health Board*).[1] In that case, a woman with insulin-dependent diabetes, claimed that her obstetrician failed to communicate the risk of shoulder

have opted for a cesarean delivery. Yet the treating obstetrician (and other expert physicians called to trial) claimed that the ensuing risk was very small and thus appropriately not communicated because a cesarean delivery is not in the maternal interest. The obstetrician reported that "...had I raised it [the risks of shoulder dystocia] with her then yes, she would have no doubt requested a caesarean section, as would any diabetic today."[1]

In its final decision, the UK Supreme Court ruled that the standard for what physicians should inform patients about the risks, benefits, and alternatives of treatment will no longer be determined by what a responsible body of physicians deems important but rather by what a reasonable patient deems important. In rendering this decision, the court swept away decades of medical paternalism in the United Kingdom to embrace a new patient-centered standard. Perhaps more compelling, the head of the Royal College of Surgeons urged that the only way to operationalize such a substantial and needed change is through shared decision making, a collaborative communication process between clinicians and patients that integrates the best evidence available with the patients' values and preferences, to promote high-quality health care decisions.

The UK law is not unprecedented. In the United States, approximately half of the states have adopted the reasonable-patient standard. The reasonable-patient standard views the informed consent communication process from the patient's perspective. It requires physicians and other health care practitioners to disclose all relevant information about the risks, benefits, and alternatives of a proposed treatment that an objective patient would find material in making an intelligent decision as to whether to agree to the proposed procedure.[2] Even in those states that apply the reasonable-patient standard, however, the informed consent process is often ill-configured to meet patients' informational needs.

Informed consent discussions are often devoid of details about the material risks, benefits, and alternatives that are critical to meaningful patient decision making. Informed consent documents for procedures, surgery, and medical treatments with material risks (eg, radiation therapy) tend to be generic, containing information intended to protect the physician or hospital from litigation. These documents are often at a high reading level and sometimes presented in nonlegible print, putting a premium on health literacy and proactive information-seeking behavior.[3] Moreover, informed consent documents are often signed minutes before the start of a procedure, a time when patients are most vulnerable and least likely to ask questions—hardly consistent with what a reasonable patient would deem acceptable. In the United States, with the exception of 1 state, Washington, that explicitly recognizes shared decision making as an alternative to the traditional informed consent process,[4] the law has yet to promote a process that truly supports a reasonable-patient–centered standard through shared decision making.

Informed Consent and High-Value, Patient-Centered Care

According to the US Centers for Disease Control and Prevention, more than 50 million surgical and nonsurgical inpatient procedures are performed each year.[5] For these patients, informed consent heralds a critical moment in the patient-physician relationship. In the process of communicating information about treatment options and the attendant risks, benefits, and alternatives, patients have an opportunity to reflect on their preferences, values, and goals; to learn more about their prognosis; and to signal concerns about safety and rehabilitation. Reasonably, patients may request more information, a second opinion, or support from a family member or friend in the decision-making process.

What would a high-value, patient-centered process for informed consent look like? A comprehensive, transparent, and hopefully bias-free communication with a trusted clinician is irreplaceable; however, it is not sufficient. Written information, whether presented on paper or mobile device, is still critical.[6] Much attention has been given to patient decision aids, or enhanced informed consent tools with information about different options for treatment. High-quality decision aids are developed and tested with patients; thus, they are intended to conform to the standards of a reasonable patient. Patient decision aids can provide balanced, evidence-based information about treatment options and usually are easy to read, often with pictures and figures; some may include patient testimonials about different pathways.

In a 2012 review of 115 studies involving more than 33 000 patients, those who engaged in shared decision making and received a decision aid (either written, electronic, audiovisual, or web-based tool formats), as compared with usual care, had greater knowledge of the evidence, felt more clear about what mattered to them, had more accurate expectations about the risks and benefits, and participated more in the decision-making process.[7] These are important outcomes of the consent process. Furthermore, early studies suggest that individuals who take a more active role in their health care decisions have a better understanding of their choices and are more likely to receive care consistent with their preferences, values, and goals.

Policy Initiatives to Advance Informed Consent With the Reasonable Patient Standard

Why then have laws espousing a reasonable-patient standard not been successful in achieving a high-value, patient-centered approach to informed decision making? One explanation may be that the health system has not previously viewed informed consent as a value-based proposition. In a systematic review of the implementation of shared decision making,[8] pervasive physician- and system-level barriers, summarized as "professional indifference" and "organizational inertia," were found, including a lack of physician comfort with decision aids, time constraints and competing priorities, lack of reimbursement, perceived

tion linking shared decision making to informed consent and promoting the use of decision aids as an alternative to standard informed consent documents.[4] Importantly, the state is partnering with stakeholders to establish certification criteria for patient decision aids, with the aim of endorsing only those decision aids that meet accepted standards for development and testing, are evidence based, and free of conflict of interest.[7] Additionally, there is support for the concomitant training of health professionals to learn how to effectively engage in shared decision making.

The Centers for Medicare & Medicaid Services (CMS) has several initiatives to support patient participation in decision making and higher-quality informed consent. For example, CMS will now reimburse for annual lung cancer screening with low-dose computed tomography, provided that a counseling and shared decision-making visit has occurred and is documented in the medical record.[9] Accountable care organizations participating in the Medicare Shared Savings Program are being evaluated on 33 quality metrics, including patient and caregiver experiences with shared decision making. The benefits of these efforts for patients, physicians, and health systems need to be evaluated.

Opportunities

This is an important moment for revitalizing reasonable-patient standards for informed consent. First, operationalizing well-intended laws will require buy-in from physicians, health systems, and payers. A starting point is to be transparent about current practices for obtaining informed consent and the potential threat to high-value, patient-centered care. For example, informed consent obtained minutes before a procedure jeopardizes patient autonomy and can lead to waste, because patients may agree to a decision they never would have made if they had the opportunity to fully consider the risks, benefits, and alternatives of the procedure. Second, expanded policy efforts are needed, such as those taking place in Washington State, that embrace shared decision making with the use of certified patient decision aids as an acceptable and preferred standard for informed consent. Third, value-based payment models that recognize high-quality informed consent practices need to be implemented and studied.

The UK case serves as a reminder that at the heart of a reasonable-patient standard is respect for p... informational needs; preferences, values, and goals; safety; and autonomy. By truly embracing this standard through the promotion of shared decision making, patients, the health system, and society will benefit.

Article Information

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Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Spatz and Krumholz report receiving support from the Centers for Medicare & Medicaid Services to develop and maintain performance measures used in public reporting programs and that they are currently developing a measure of informed consent document quality. Dr Krumholz reports receiving research agreements from Medtronic and from Johnson & Johnson (Janssen), through Yale University, to develop methods of clinical trial data sharing and chairing a cardiac scientific advisory board for UnitedHealth. Mr Moulton reports that he is employed by the nonprofit organization Healthwise Inc, which produces and distributes patient education materials, and serves on a technical expert panel to provide feedback on a measure of informed consent document quality, funded by the Centers for Medicare & Medicaid Services.

Funding/Support: Dr Spatz is supported by grant K12HS023000 from the Agency for Healthcare Research and Quality Patient-Centered Outcomes Research Institute (PCORI) Mentored Career Development Program. Dr Krumholz is supported by grant U01 HL105270-05 (Center for Cardiovascular Outcomes Research at Yale University) from the National Heart, Lung, and Blood Institute.

Role of the Funder/Sponsor: The funding organizations had no role in the preparation or review of the manuscript or the decision to submit the manuscript for publication.

Disclaimer: The views presented in this article reflect those of the authors and not those of the funders/sponsors.

References

1. *Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)*, [2015] UKSC 11, on appeal from [2013] CSIH 3; [2010] CSIH 104 (2015).
2. *Janine Harnish v Children's Hospital Medical Center & others*, 387 Mass 152 (1982).
3. Hopper KD, TenHave TR, Tully DA, Hall TE. The readability of currently used surgical/procedure consent forms in the United States. *Surgery*. 1998;123(5):496-503. PubMed | Google Scholar | Crossref
4. Washington State Legislature. Consent Form—Contents—Prima Facie Evidence—Shared Decision Making—Patient Decision Aid—Failure to Use. Title 7, Chapter 770, Section 770060. Washington State Legislature website. http://app.leg.wa.gov/rcw/default.aspx?cite=7.70.060. Accessed March 17, 2016.

2010. CDC website. http://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberprocedureage.pdf. 2010. Accessed March 17, 2016.

6. Krumholz HM. Informed consent to promote patient-centered care. *JAMA*. 2010;303(12):1190-1191.
Article | PubMed | Google Scholar | Crossref

7. Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014;1:CD001431.
PubMed | Google Scholar

8. Elwyn G, Scholl I, Tietbohl C, et al. "Many miles to go …": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inform Decis Mak*. 2013;13(suppl 2):S14.
PubMed | Google Scholar | Crossref

9. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT) (CAG-00439N). CMS website. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274. 2015. Accessed March 11, 2016.

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