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The New Era of Informed Consent: Getting to a Reasonable Patient Standard through Shared Decision Making

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The rights of patients to be informed about care decisions in clinical practice is yet again under scrutiny. 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 United Kingdom (UK) Supreme Court case (Montgomery vs. Lanarkshire Health Board).[1] Montgomery, a woman with insulin-dependent diabetes, claimed that her obstetrician failed to communicate the risk of shoulder dystocia associated with the vaginal delivery of her baby with macrosomia, a complication that ultimately resulted in severe brain anoxia. She claimed that had she had full information about the risks, she would have opted for a caesarean 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 caesarean delivery is not in the maternal interest. The obstetrician reported, "… 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."

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 reasonable physician 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 UK 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 U.S., 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 the provider to disclose all relevant information about the risks, benefits and alternatives of a proposed treatment that an

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objective patient would find material in making an intelligent decision as to whether to agree to the proposed procedure.[2] Even in the 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 (e.g., radiation therapy) tend to be generic, containing information that is intended to protect the physician or hospital from litigation. These documents are often written at a high reading level and sometimes presented in non-legible print, putting a premium on health literacy and pro-active 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 U.S., with the exception of one 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 U.S. Centers for Disease Control and Prevention, more than 40 million elective procedures are performed each year. For these patients, informed consent heralds a critical moment in the physician-patient 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.[5] 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 over 33,000 patients, those who engaged in shared decision making and received a decision aid (either written, electronic, audio-visual or web-based tools 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.[6] Furthermore, early studies suggest that people who take a more active role in their healthcare decisions have a

better understanding of their choices, and are more likely to receive care that is 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,[7] 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 burden; and cost. Only recently, policy-makers are providing tangible incentives to promote informed consent that conform to a reasonable patient standard. Washington State, for example, has enacted legislation 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.[6] 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 and 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 CT provided that a counseling and shared decision making visit has occurred and is documented in the medical record.[8] 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 needs to be evaluated.

Opportunities

This is an important moment for revitalizing reasonable patient standards for informed consent. Operationalizing well-intended laws will require buy-in from physicians, health systems and payors. 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, as patients may agree to a decision they never would have made had they had the opportunity to fully consider the risks, benefits and alternatives of the procedure. Second, we need expanded policy efforts, such as those taking place in Washington, 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 patients' 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.

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