In her *Health Affairs* Blog post last fall, Sharon Brownlee lamented how frequently patients agree to treatments that they know little about. In the United States and elsewhere, clinicians have a clear ethical and legal responsibility to obtain informed consent for tests, treatments, and procedures. Too often, however, clinicians fail to describe risks adequately or to present alternatives. This meets neither the letter nor the spirit of the law; yet as long as there is a signature on a form, the adequacy of informed consent is rarely questioned.
Brownlee largely laid the blame at the feet of clinicians who do not convey the information effectively. It is true that clinicians do not always make themselves understood. Thirty percent of adults report that they do not always find their providers easy to understand, and more than 70 percent of adults report that their health care providers do not always check their understanding of instructions. Clinicians, however, cannot fulfill their responsibilities for informed consent without the support of systems they work in.

**Informed Choice: A Needed Paradigm Shift**

As the lead for health literacy at the Agency for Healthcare Research and Quality (AHRQ) and co-chair of the Health and Human Services Health Literacy Workgroup, I champion clear communication and patient engagement. I’m an adherent of the slogan popularized by quality improver Don Berwick, “Nothing about me without me.” I believe that if we are to overcome the inherent power differential between clinicians and patients, we need a paradigm shift. The current state of affairs, whereby people commonly consent to treatments their clinicians recommend without full information, needs to be transformed into a proactive one of informed choice.

Informed choice requires:

- Easy-to-understand information about the benefits, risk, and harms of all options;
- Eliciting patients’ and families’ goals and values; and
- Impartial help with making the decision.

There are those who argue that some people don’t want to make health care decisions themselves; they prefer to let their clinicians decide for them. Data presented at the National Academy of Medicine, however, showed that many people who initially say they are not interested in sharing in the decision making change their minds when they are told that the information about their options will be clear. People are ceding their decision-making authority because they anticipate being given information that is confusing or incomprehensible.

**Address Health Literacy: A Prerequisite To Informed Choice**

Making information about treatment options understandable is challenging. More than one-third of adults in the US have limited health literacy, meaning they have difficulty understanding and using health information. That number soars to 70 percent for adults older than age 75. People have even more difficulty understanding numbers and risk.
However, when careful attention is paid to how numeric information is presented, less numerate people can understand.

Health care professionals need to take health literacy universal precautions, which means treating everyone as if they are at risk of misunderstanding. This requires using health literacy strategies, such as speaking in plain language and encouraging questions, with all patients. Universal precautions are warranted because clinicians are not good at identifying who has limited health literacy. Furthermore, everyone is susceptible to limited health literacy at times. For example, anyone making a medical decision can be frightened, sleep-deprived, or feeling ill—all of which can reduce their ability to process information.

An important aspect of health literacy universal precautions is checking that patients and families have understood the information they have been provided. The teach-back method, whereby people are asked to describe in their own words what they have been told and are re-taught until they can do so successfully—is recommended by the National Quality Forum and The Joint Commission for confirming understanding in the informed consent process.

Elicit And Honor Patient Preferences: A Way To Prevent Preference Misdiagnosis

Informed choice means that patients and families make decisions that are consistent with their goals and values. Some clinicians believe that patient and family preferences have a role in decision making only in limited circumstances, when treatments are so-called “preference sensitive.” Authors of a Health Affairs article contrasted preference sensitive treatments with “effective” treatments, for which the benefits far outweigh the possible harms. What they fail to acknowledge is that for many treatments, people can disagree about whether the benefits outweigh the harms, and this can depend on what their treatment goals are. Some people may want to minimize pain, while others may prefer to get back to work or school quickly or be able to return to a favorite activity. People also vary in their willingness to tolerate side effects or risks of bad outcomes. Only the patients and their families can make these tradeoffs.

Too often clinicians make incorrect assumptions about what patients want and advise them to have treatments that patients would refuse if they were fully informed and empowered. The name for this, when clinicians mistakenly think they know what patients want, is preference misdiagnosis. For example, Dina Keller Moss eloquently and powerfully related in a “Narrative Matters” article how she helped her terminally ill mother
avoid having a surgery that would have made her life miserable. The surgeons were well intentioned; they wanted to give their patient a longer life. They just didn’t understand how poor the quality of that life would feel to her.

Although most clinicians agree that patient and family preferences should be elicited and honored, not all do. In a small study of clinicians at several hospitals, researchers found that 10 percent of clinicians did not agree with the statement, “Clinicians should encourage patients to talk about their values,” and 20 percent did not agree with the statement, “Lack of patient understanding of benefits, harms, and risks of treatments is a serious patient safety problem.” Forty-five percent of clinicians thought that “Clinicians are in a better position than patients to decide what patients need.”

Clinicians’ actions mirror their attitudes. A significant minority of clinicians does not usually or always follow best practices in informed consent. By their own admission, 15 percent of clinicians in the above study never or only sometimes: engage patients, family, and friends in the consent discussion or elicit goals and values. Forty-five percent reported never or only sometimes using high-quality patient decision aids, which can be a means of eliciting goals and values.

**Helping Make The Decision: A New Clinical Role**

Patients and families need help in aligning their preferences with options. As I described in a “Narrative Matters” article, when hospital residents strongly advocated for a treatment I was uncertain my father needed, “I needed someone to serve as an unbiased interpreter of the evidence, to recognize my knowledge of this particular patient, and to ask about our values and goals. I needed someone to acknowledge that we faced a hard decision, that there were no guarantees, and that it was ultimately our choice.” While clinicians are the authorities on the medical evidence, patients are the experts in themselves. Clinicians who understand this help patients and families with their choices, providing information in an evenhanded manner. Providing complete, impartial information, however, can be difficult.

Legally, the clinician who is delivering a treatment or performing a procedure is the one required to obtain consent. However, that person is not necessarily knowledgeable about the other options nor are they a disinterested party. The informed choice paradigm prompts us to consider creative ways of helping patients and families reach a decision. For example, health systems can explore innovative solutions such as using embedded conversational agents (avatars) to deliver education and clarify choices, peer counselors to guide patients and families in their deliberations, and consent teams that assemble all the requisite expertise, ensure neutrality, and check patient understanding.
Getting To Informed Choice

Achieving a paradigm shift does not happen spontaneously. Health care professionals and leaders, regulators and payers, and patient and families all have a role to play.

Training Leadership And The Front Line

Training clinicians in how to communicate clearly, engage patients and families, and provide complete and neutral explanations is part of the solution. That’s why AHRQ’s Making Informed Consent an Informed Choice Training Module for Health Care Leaders and Professionals teaches 10 strategies for communicating clearly and presenting choices. Training clinicians is necessary, but not sufficient, to establish informed choice as the new normal. Clinicians with the desire and skills may not be able to afford their patients an informed choice without the support of the systems in which they work.

Health systems that wish to embrace and operationalize informed choice have to create and communicate clear policies, establish efficient workflows, and provide resources such as easy-to-understand forms, high-quality decision aids, and language assistance. For this reason AHRQ’s Making Informed Consent an Informed Choice: Training for Health Care Leaders and Professionals provides a roadmap for making these system-level improvements. The Implementation Guide for AHRQ’s Making Informed Consent an Informed Choice Training Modules helps organizations use a quality improvement approach to smooth the transition to informed choice.

Addressing Preference Misdiagnosis With Patient Decision Aids

It is a medical error when patients have procedures that they would not have chosen if they had fully understood all the relevant information. While there are initiatives to improve medical diagnostic safety, we do not see commensurate efforts to prevent preference misdiagnosis, despite the associated harms. High-quality patient decision aids are one means of reducing preference misdiagnosis. Not only do they present clear, unbiased information about options, they also help patients clarify their goals and values. There are, however, no safeguards preventing parties with vested interests from developing decision aids that promote choices that maximize revenues or cut costs. In the absence of an impartial certification process, health systems have to select patient decision aids carefully to ensure only high-quality ones are used.

Standard Setting And Enforcement
Both The Joint Commission and the Centers for Medicare and Medicaid Services (CMS) have standards regarding informed consent. For example, CMS states that patients have the right to make informed decisions regarding their care and that they should “receive adequate information, provided in a manner that the patient or the patient’s representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.” Both enforce their standards by having surveyors who check if facilities have informed consent policies in place and follow them. If regulators gave a higher profile to these standards by adopting and enforcing a stronger standard that assessed the adequacy of the informed consent policy, it could stimulate improvements that support informed choice.

Realigning Payment

The fee-for-service system creates financial incentives for clinicians to encourage patients to have costly tests and procedures. One problem, noted by the National Commission on Physician Payment Reform, is that physicians are overpaid for procedures, relative to what they are paid for evaluation and management services (for example, taking medical and symptom histories, medical decision making). A realignment of those payments would allow clinicians to take the time needed to inform patients and families fully about their choices and reduce the incentive to overtreat.

Making Prices Transparent

The price of tests, procedures, and treatments is rarely discussed, yet the out-of-pocket costs can impact patient and family preferences. Seventy percent of Americans report wanting to have conversations about the costs of care with their health care providers, but only 28 percent report doing so.

In a Health Affairs Blog post, Emmy Ganos and colleagues noted that patients are often waiting for their providers to start the conversation. Providers, on the other hand, feel ill at ease and ill equipped to have conversations about cost. Since patients and families need to know what they will have to pay before making a decision, organizations that want to make informed consent an informed choice have to figure out how to give patients easy-to-understand, comparable price information for each option. Practice briefs that came out of the Robert Wood Johnson Foundation’s Cost Conversations projects can help health systems work toward price transparency.

Partnering With Patients And Families
My personal encounters with the health care system have underscored the importance of health care providers partnering with patients and families as valuable members of the care team. Many people, particularly those from backgrounds where cultural norms dictate deference to doctors as a sign of respect, may not feel empowered to assert their preferences. Health systems must actively engage patients and families in the decision-making process.

Health systems trying to champion the right to make informed choices should also think about patients and families as quality improvement partners. Organizations such as the Institute for Patient- and Family-Centered Care can help guide systems’ inclusion of patients and families in the improvement process.

A paradigm shift is when the usual way of thinking about or doing something is replaced by a new and different way. Often, it is thought of as a dramatic transformation. But paradigm shifts can be the result of incremental progress until a tipping point is reached. The US health promotion program Healthy People has tracked progress in one aspect of making informed choice a reality. The percentage of people who said their health care providers always involved them in decisions about their health care as much as they wanted has increased from 51.6 percent in 2007 to 56.8 percent in 2017. We need to accelerate the pace, but the change is in the right direction.