NQF

NATIONAL QUALITY FORUM

Implementing a National Voluntary Consensus Standard for Informed Consent

A User's Guide for Healthcare Professionals

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National Quality Forum
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INTRODUCTION

Many people do not understand basic, important information about their healthcare decisions – particularly people with limited English proficiency, low educational attainment, and cognitive impairments.

Informed consent is a means to ensure that all patients understand and agree to the potential consequences of their care. This user's guide describes how to improve the informed consent process to ensure that patients understand the choices they make. The purpose of this guide is two-fold:

- to bring together in one place the compelling evidence demonstrating the need for better informed consent and the benefits of adopting Safe Practice 10 for improving it; and
- to provide healthcare professionals with the information and tools they need to adopt Safe Practice 10 within their organizations.

The information in this user's guide is organized into the following sections:

WHAT IS THE PROBLEM?

Many patients do not understand basic information about their care

Nearly half of all American adults (47 percent)—90 million people—have limited health literacy, which restricts their capacity to obtain, process, and understand the basic health information and services that are needed to make appropriate health decisions.[1]

The majority of American adults with limited literacy are native-born, Caucasian, English speakers. Those with limited literacy come from all races, ethnicities, genders, ages, and socioeconomic levels, but health literacy tends to be lower for those with limited English proficiency (LEP), cognitive impairments, learning disabilities, and low educational attainment, and for the poor, the elderly, and some minority groups.[1]

The concept of informed consent is based upon a patient's right to be fully informed about the consequences of the healthcare treatment he or she chooses to receive. However, despite a common perception held by many healthcare professionals that they communicate effectively at a basic level, a large number of patients still do not comprehend critical information about their care because of factors such as limited health literacy, stress, emotional distress, or personal or cultural beliefs.

Even those who appear to understand may not truly be informed

A patient's informed consent is required for all surgical procedures and some forms of medical treatment. Although providers often believe that a patient's signature on a form is sufficient to ensure that he or she provided informed consent, studies show that even after agreeing to or receiving care, 18 to 45 percent of patients are unable to recall the major risks of surgery,[2,3,4] many cannot answer basic questions about the services or procedures they agreed to receive,[5,6,7] 44 percent do not know the exact nature of their operation,[8] and

most do not read (60 to 69 percent)[4,7] or understand (60 percent)[9] the information contained in informed consent forms, despite signing them. These patients are **not** truly informed about the choices they make.

The consequences of providing care when informed consent has not truly been achieved can be severe

Lack of true informed consent for patients receiving medical and surgical care is a common basis for malpractice cases, increases the chance of a patient safety incident or medical error, and disproportionately affects patients who have more difficulty understanding healthcare information, such as those with LEP or low literacy. Furthermore, it violates healthcare providers' professional and ethical obligations to communicate clearly with patients and allow them to make informed decisions about their care. Improving the informed consent process is a critical step that healthcare providers must take to advance quality and safety.

WHAT CAN YOU DO TO IMPROVE INFORMED CONSENT?

This guide offers healthcare professionals a practical set of tools, based on national consensus standards, for improving communication, quality, and safety in the informed consent process for patient care.*,#

Healthcare providers, including physicians, nurses, interpreters, and others, can learn how to communicate better, improve the quality of their informed consent discussions with patients, and apply these lessons to other settings in which clear communication is essential.

Administrators working in healthcare facilities, including those involved in safety, quality improvement, risk management, ethics, patient education, and interpreter services, and clinical department leaders can improve the informed consent policies and processes within specific departments or across their organizations.

A National Standard for Informed Consent: Safe Practice 10

Safe Practice 10 is one of 30 practices in the National Quality Forum's (NQF's) 2003 report *Safe Practices for Better Healthcare,* which endorsed a set of national voluntary consensus standards designed to improve patient safety throughout the healthcare system.[10] The objective of Safe Practice 10 is to ensure that patients or legal surrogates understand proposed treatments

* This user's guide contains general implementation guidance for Safe Practice 10, but the guide is not a voluntary consensus standard as defined under the National Quality Forum Consensus Development Process v1.7.

This guide may contain information that is useful in the informed consent process for research subjects, but it is designed primarily for use in non-investigational, patient care settings.

and their potential complications, and it calls for healthcare professionals in all care settings to:

Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.

Additional specifications:

1. Use informed consent forms written in simple sentences and in the primary language of the patient.
2. Engage the patient in a dialogue about the nature and scope of the procedure covered by the consent form.
3. Provide an interpreter or reader to assist patients with limited English proficiency, visual or hearing impairments, and low literacy.
4. Convey the higher risk associated with suboptimal volumes for select high-risk surgeries and procedures as specified in [Safe] Practice 2.[+]

[+] The high-risk surgeries and procedures are coronary artery bypass graft, coronary artery angioplasty, abdominal aortic aneurysm repair, pancreatectomy, esophageal cancer surgery, and high-risk deliveries (those with expected low birth weight [<1,500g], those that are premature [<32 weeks gestation], or those that involve correctable major congenital anomalies).

HOW IS THIS PRACTICE USED?

Individual providers can start using this practice now by using the instructional card, *A Provider's Guide to Informed Consent,* included with this guide.

Healthcare administrators and professionals seeking to implement this practice at their organizations can use this general Plan-Do-Check-Act (PDCA) model:

Recommended Steps for Implementing Safe Practice 10

	Component	Examples - Who/What/How
Plan	Identify where this fits in into your organization's priorities	Patient safety, ethics, cultural competency, quality improvement, risk management, regulatory/ accreditation compliance
	Get the support of clinical and administrative leaders. Identify someone to "champion" this effort to ensure its success	Hospital administrator, chief of surgery, nursing leader, risk manager, interpreter services director
	Assess your informed consent policies, processes, and forms to determine what changes are needed to incorporate Safe Practice 10	Translating/simplifying consent forms, dedicating staff time/resources to monitor and implement change, hiring additional interpreters, changing standard procedures for obtaining consent
	Identify what steps are needed for the needed changes to occur at the organization	Review and approval of policies, processes, and forms by hospital committees and leaders
	Determine who will use Safe Practice 10 and how. Clearly define roles and responsibilities of all involved personnel	Physicians (resident and attending), nurses, interpreters, and others who communicate with patients about their healthcare decisions

Recommended Steps for Implementing Safe Practice 10 *(continued)*

	Component	Examples - Who/What/How
Plan continued	Outline when Safe Practice 10 should be used in the care process	To support meaningful patient decisionmaking, use it early and often by various providers in the process. Avoid waiting until the day of surgery, if possible, except as an extra safety check
	Determine how compliance will be measured and enforced	Patient survey, documentation on the consent form or patient chart that "repeat back" was attempted, successful, or what information patients recounted
Do	Implement changes to the process, policies, and/or forms within the appropriate setting(s)	Consider starting with a pilot project in one unit (e.g., elective surgery) or with a few willing providers before expanding more broadly across the organization
	Educate those who will be responsible for using Safe Practice 10 on what the changes are, why they are important, and what actions must be taken	Circulate and post copies of *A Provider's Guide to Informed Consent,* send e-mail notices, incorporate into ongoing training requirements for existing personnel and new employee orientation, present information at staff meetings
Check	Evaluate the level of compliance with the revised processes, policies, and/or forms	Audit consent forms or patient charts for documentation, if required
	Assess the general level of buy-in and support for those responsible for using Safe Practice 10, including benefits and areas for improvement	Collect and share examples of the benefits and lessons learned for quality improvement and to increase buy-in by others

Recommended Steps for Implementing Safe Practice 10 *(continued)*

	Component	Examples - Who/What/How
Act	Develop and carry out strategies to improve provider buy-in and compliance	Perform additional education, and use heavier enforcement mechanisms if needed
	Ensure that a sustainable, long-term plan and resources exist for ongoing compliance monitoring and for educating providers	At least one primary individual at the organization must be assigned an active role in ensuring the changes are sustained
	Expand the use of Safe Practice 10 and other informed consent process improvements more broadly	Modify the PDCA cycle for widespread implementation across the organization

WHY SHOULD YOU USE SAFE PRACTICE 10?

Joint Commission on Accreditation of Healthcare Organizations Accreditation and Medicare Conditions of Participation

Informed consent is addressed in federal guidelines on the Conditions of Participation that hospitals must meet to be reimbursed under Medicare. The guidelines note that, "an authorization from a patient who does not understand she he/she is consenting to is not informed consent."[11] Improvements in provider-patient communication and your informed consent process will address existing Joint Commission on Accreditation of Healthcare Organizations (JCAHO) goals and accreditation standards, such as:

- *Priority Focus Areas* – include communication and the degree to which organizations' communication processes affect safety and quality.
- *National Patient Safety Goals* – address communication and wrong-site, wrong-patient, wrong-procedure surgery; "teach back" could be used to confirm that this basic information is a well-established patient safety practice.
- *Accreditation standards RI.2.40, RI.2.100, and PC.6.10* – address requirements for adequate informed consent, communication, and patient education.

Professional, Legal, and Ethical Duty

The American Medical Association[12] and many state and other professional medical groups' codes of conduct name informed consent as an ethical obligation of physicians. Furthermore, adequate communication to support informed decisionmaking is a legal requirement contained in state statues or established by case law in all 50 states,[13] and a signed form may not be sufficient to prove informed consent was obtained. Evidence that patients did not adequately understand information required for informed consent can and has been the basis

for a number of medical malpractice suits ruled in the patient's favor;[1,14,15] according to Jury Verdict Research, informed consent is one of the top 10 most common reasons for medical malpractice suits.[16]

Healthcare Purchaser Demand: The Leapfrog Group Survey

The Leapfrog Group is a consortium of more than 170 private and public healthcare purchasers that combined provide health benefits for more than 36 million Americans and spend more than $67 billion each year on healthcare. The group surveys hospitals nationwide to assess the degree to which they use the 30 practices in *Safe Practices for Better Healthcare,* and its members work to select and reward providers based on the extent to which they use those practices, including Safe Practice 10. One-third of all hospitals responding to the Leapfrog Group's 2004 survey (287 out of 862 hospitals) reported that they have fully implemented programs to help meet the goals of Safe Practice 10.[17]

CASE STUDIES OF THE BENEFITS OF "TEACH BACK"

In 2004, NQF evaluated the informed consent processes of four hospitals that had adopted Safe Practice 10, particularly the "teach back" component (these findings are detailed in the NQF report *Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy*[18]). Some of the benefits of "teach back" are illustrated in these examples:

Quality, Patient Safety, and Risk Management

- A Spanish-speaking woman walked out of the hospital just prior to surgery when it was finally communicated clearly to her that tubal ligation was a permanent sterilization technique, not a temporary method of birth control.
- A diabetic patient's chart was flagged when providers noted he had difficulty teaching back pre-operative medication use instructions; the surgery was delayed when his glucose levels were found to be dangerously high.
- The planned anesthesia for a patient was incompatible with Coumadin, but the patient did not report use of Coumadin until "teach back" was used at a late stage of the pre-operative process, allowing providers to avoid a potentially fatal interaction.
- A number of patients, when asked to recount information about their surgery, named a different side of the body or a different type of surgery than what was indicated on their charts, prompting providers to check again to confirm what was correct.
- The providers and departments that used "teach back" routinely were widely recognized by their peers as having the most well-informed patients, compared with other departments that did not use "teach back" in communicating with patients.

Cost/Efficiency

- Although the time burden involved in asking patients for "teach back" may seem high, providers anecdotally reported that "teach back" typically takes less than one minute to complete, particularly once they became more proficient at using the communication practice. Studies also have reported that encounters that included assessments of patients' recall or comprehension were no longer than those without them.[19]
- Four months after starting to use "teach back," one hospital department, which frequently saw 100 patients per day, dropped the surgical cancellation delay rate from 8 percent to 0.8 percent, resulting in a savings of $56/minute for the resources that previously had been wasted by cancelled or delayed surgeries.

HOW WAS SAFE PRACTICE 10 DEVELOPED?

Safe Practice 10, as one of the 30 practices in *Safe Practices for Better Healthcare*, was endorsed by NQF through its formal Consensus Development Process,[20] which involves the input, review, and vote of the NQF membership. NQF Members included 155 organizations at the time the report was endorsed in 2003, and currently more than 260 organizations are NQF Members, representing national and local healthcare providers, health plans, researchers, quality improvement groups, accreditation and regulatory bodies, public and private purchasers, and consumer advocates. NQF endorsement of Safe Practice 10 confers upon it unique legal standing as a voluntary consensus standard, which allows it to be more readily adopted by the federal government and other bodies.

NQF endorsed *Safe Practices for Better Healthcare* after an intensive process that included a comprehensive evidence review,[21] Steering Committee meetings held over two years, and additional review, comment, and revision based on the feedback of NQF Members and the general public. Following the report's release, NQF undertook an effort to accelerate the adoption of Safe Practice 10 specifically, given its high priority for vulnerable populations. A comprehensive report describing the experiences of several "early-adopter" hospitals of Safe Practice 10 and detailing a variety of recommendations is available in *Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy.*[18]

The Evidence Base for Safe Practice 10

"Teach Back"

Studies show that patients who are asked to recount—also known as "teach back," "repeat back," or the "show me" technique—have greater recall and comprehension of the risks and benefits of surgical procedures than those who are not asked to recount;[5,21] one study found that three times as many patients could recall this information after surgery if asked for "teach back" before the procedure.[22]

"Teach back" is widely recommended by many experts as an effective mechanism for communicating with patients with low literacy[19,23,24,25,26,27,28] because it increases patient retention, gives providers a gauge of how well patients understand information, and actively involves patients in the discussion. Organizations that voted for "teach back" to be endorsed as a national standard by NQF have included the American Academy of Family Physicians, the American College of Surgeons, the American Hospital Association (AHA), the American Nurses Association, the Federation of American Hospitals, and JCAHO.

Simplified and Translated Forms

Most informed consent forms are written at levels that are too high for the average American to understand. Simplification of these forms to at or below the fifth-grade reading level will increase understanding and recall of information about medical procedures for patients across all levels of health literacy.[27,29,30,31] Use of universal symbols, pictures, and other educational aids also may be beneficial, especially for patients who are illiterate or who have English language barriers.

Federal regulations require adequate interpretation and translation services for individuals with LEP at institutions receiving federal funding,[32] and federal guidance recommends that "vital written materials," including consent forms, be translated into languages spoken by 5 percent or 1,000 of a provider's patients, whichever is less.[33]

Engaging Patients in a Dialogue

Personal interactions allow patients to be engaged in their care decisions, and these interactions are needed to supplement the consent form. This is because even simplified or translated consent forms alone are not sufficient for improving comprehension.[34]

Providing Interpreters or Readers

For patients with LEP in particular, qualified medical interpreters are key to ensuring that clear communication occurs. This is because unskilled interpreters are much more likely to make errors that have patient safety implications.[35] Federal regulations call for the use of competent interpreters and note that patients' family and friends should not be used, because the accuracy and objectivity of their interpretation is known to be highly biased and problematic.[35]

Volume-Outcome Disclosure

When patients agree to surgery, their consent is based partially on information providers give them about the expected risk of complications and adverse outcomes. Because mortality has been shown to vary significantly based on provider volume for several high-risk surgeries,[10] disclosure of that volume-outcome relationship is critical to support patient decisions based on expected risks.

In recognition of patients' right to be informed about providers' volume and outcome data when making choices about where to receive surgery, several states (including New York and Pennsylvania) already mandate that providers report these data, which are made available publicly. National organizations and federal entities also are pursuing public reporting of these data through initiatives led by groups such as AHA and the Centers for Medicare and Medicaid Services. Furthermore, evidence-based hospital referral for the procedures referenced in Safe Practice 10 is one of the three core patient safety practices of the Leapfrog Group.

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ADDITIONAL RESOURCES

National Quality Forum	www.qualityforum.org *(includes the Consensus Development Process, information on other NQF standards and publications, list of Member organizations, and Board of Directors)*
The Commonwealth Fund	www.cmwf.org
Informed Consent	
Bibliography of resources	www1.va.gov/resdev/resources/pubs/informed_consent
Limited English Proficiency	
Executive Order 13166: Improving Access to Services for Persons with Limited English Proficiency	www.usdoj.gov/crt/cor/pubs/eolep.htm
Implementation guidance for Executive Order 13166	www.lep.gov
Health Research & Educational Trust toolkit for collecting race, ethnicity, and primary language information from patients	www.hretdisparities.org
Modern Language Association map of languages in the United States	www.mla.org/census_main
National Council on Interpreting in Health Care	www.ncihc.org
Health Literacy	
American Medical Association Foundation	www.amafoundation.org
U.S. Census, American Community Survey*	www.census.gov/acs
Partnership for Clear Health Communication	www.askme3.org/pfchc
Institute of Medicine, *Health Literacy*	www.iom.edu/project.asp?id=3827

An expanded list of resources, this user's guide, and additional cards, *A Provider's Guide to Informed Consent,* are available at www.qualityforum.org.

* Provides regional-level population data, including levels of educational attainment, which may be used to estimate literacy levels.

THE NATIONAL QUALITY FORUM (NQF) is a private, nonprofit, open membership, public benefit corporation whose mission is to improve the American healthcare system so that it can be counted on to provide safe, timely, compassionate, and accountable care using the best current knowledge. Established in 1999, NQF is a unique public-private partnership having broad participation from all parts of the healthcare industry. As a voluntary consensus standards setting organization, NQF seeks to develop a common vision for healthcare quality improvement, create a foundation for standardized healthcare performance data collection and reporting, and identify a national strategy for healthcare quality improvement. NQF provides an equitable mechanism for addressing the disparate priorities of healthcare's many stakeholders.

A PROVIDER'S GUIDE TO INFORMED CONSENT

National Quality Forum's Safe Practice 10

Q: How do you know if patients have given *informed* consent?

A: You *don't* – unless they can tell you what they have agreed to receive.

To ensure that patients understand proposed treatments, services, and procedures and give true informed consent, providers should:

Ask all patients (or their legal surrogates) to verbally *"teach back"* information about the treatments, services, and procedures for which they have been asked to give informed consent.

Who Physicians, nurses, interpreters, and other professionals who communicate with patients about their healthcare decisions in the informed consent process should use "teach back" for all patients, especially those who may have difficulty understanding even basic health information.

What Patients should be able to explain, in everyday words:

- the diagnosis/health problem for which they need care;
- the name/type/general nature of the treatment, service, or procedure, including what receiving it will entail; and
- the risks, benefits, and alternatives to the treatment, service, or procedure.

When Ask for "teach back" early in the care process (i.e., well before the day of surgery, whenever possible), so that patients have time to think about their options and make informed choices.

Why Many patients have difficulty understanding basic health information, despite signing consent forms. Asking for "teach back" helps you gauge how well patients understand and whether informed consent was really given.

How Patients should be able to show they *understand* and not just be asked to pass a "quiz" or to repeat what you said. Use phrases such as:

- "I want to be sure we have the same understanding…."
- "It's my job to explain things clearly. To make sure I did this…."
- "This is important for your safety…."
- "Can you tell me, in your own words…?"

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Common Misperceptions by Providers

- Asking patients "do you understand?" or "do you have any questions?" will **not** tell you whether they really understand.
- Informed consent is a communication process, not a paper form. Getting patients to sign consent forms does not mean they have read them or that they understand what they consented to receive, and it may **not** be enough to protect you against liability. If patients do not actually understand, they have not given informed consent.

Other Steps for Better Informed Consent

- Use informed consent forms written in simple sentences and in the primary language of the patient.
- Engage patients in a dialogue about the nature and scope of the procedure covered by the consent form.
- Provide an interpreter or reader to assist patients with low literacy or limited English proficiency and patients who are visually or hearing impaired.
- Convey the higher risk of adverse outcomes for certain high-risk surgeries and procedures for which there is evidence linking volume to outcomes:
  - coronary artery bypass graft,
  - coronary artery angioplasty,
  - abdominal aortic aneurysm repair,
  - pancreatectomy,
  - esophageal cancer surgery, and
  - high-risk deliveries (those with expected low birth weight [<1,500g], those that are premature [<32 weeks gestation], or those that involve correctable major congenital anomalies).

These materials on Safe Practice 10 are based on national consensus standards for patient safety endorsed by

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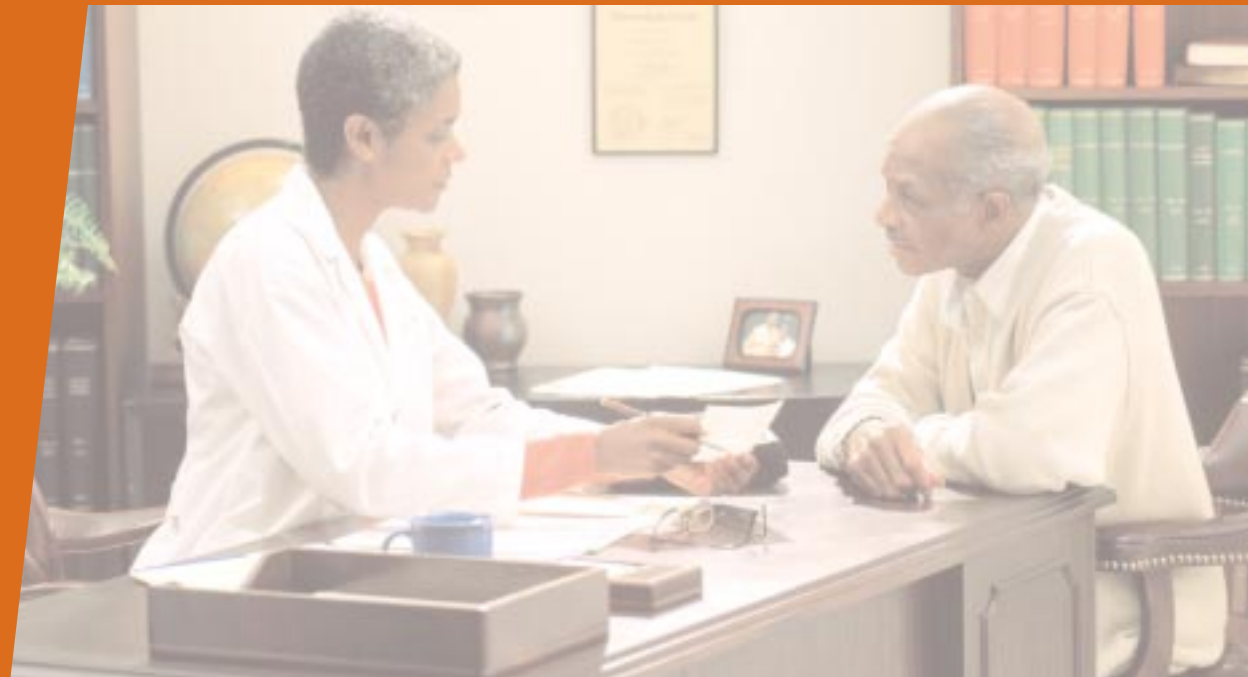

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