



NATIONAL QUALITY FORUM

**Improving Patient
Safety Through
Informed Consent for
Patients with Limited
Health Literacy**

AN
IMPLEMENTATION
REPORT

NQF

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Foreword

Informed consent is a central element of safe, high-quality healthcare. Well-informed patients are more likely to receive care that reflects their personal preferences and values, and they are better prepared to provide necessary self-care. Well-informed patients tend to be more satisfied with their care and to be more trusting of their caregivers. Conversely, poorly informed patients—whether due to limited English language proficiency or limited health literacy—are at increased risk of suffering from a medical error or poor-quality care.

In May 2003, the National Quality Forum (NQF) published *Safe Practices for Better Healthcare*, a report specifying 30 evidence-based practices that would substantially reduce the risk of healthcare errors. Among these 30 practices, Safe Practice 10—which calls for improved communication in the informed consent process—stood out because of its relevance across clinical areas, its focus on patient-centered care, and its importance to patients who are vulnerable to receiving poor-quality care because of communication barriers.

Informed consent is particularly important to NQF because it is an essential component of addressing the problem of healthcare disparities. In December 2003, NQF launched a project aimed at facilitating provider adoption of Safe Practice 10. The project focused on informed consent for elective, invasive procedures, and particularly concentrated on patients with limited health literacy. This report contains a comprehensive synthesis of the key lessons learned by providers that adopted Safe Practice 10, including detailed case studies of three “early adopters” and feedback from providers who have not yet adopted the practice. Based on these findings, a separate user’s guide was developed to assist providers in implementing Safe Practice 10.

NQF thanks The Commonwealth Fund for its support of this project; the participating healthcare organizations for their generous commitment of time and for allowing us access to their facilities; and the participants of this project’s workshop for their thoughtful feedback.

NQF and its more than 260 Member organizations are committed to advancing the quality of healthcare in the United States for all and believe that those for whom communication barriers present a risk of poor-quality care should receive special attention.



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President and Chief Executive Officer

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Table of Contents

Executive Summary	vii
Introduction	1
Project Overview.....	3
Safe Practice 10: An NQF-Endorsed Voluntary Consensus Standard	3
Study Method	4
Project Outcomes.....	6
Using Safe Practice 10: Four Hospitals’ Experiences.....	7
Table 1 – Summary of Adopter Hospitals’ Implementation and Use of “Teach Back”	8
Adopter Hospitals’ Success Stories: Benefits of Safe Practice 10.....	15
Perceived Barriers and Potential Solutions to Implementation and Use	19
Key Findings and Recommendations	25
Conclusion	29
Acknowledgments.....	29
References	30
Appendix A – Project Staff, Collaborating Hospital Representatives, Technical Advisory Panel, Workshop Participants, and Non-Adopter Interviewees	A-1
Appendix B – Case Study: Early-Adopter Hospitals and Self-Assessment Protocol.....	B-1
Appendix C – Case Study: Pilot-Adopter Hospital.....	C-1
Appendix D – Case Study: Non-Adopter Healthcare Organizations and Interview Protocol.....	D-1
Appendix E – Workshop Proceedings.....	E-1

NATIONAL QUALITY FORUM

Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy

Executive Summary

Adverse healthcare events are a leading cause of injury and death in the United States, even though well-documented methods are available that could prevent their occurrence. In May 2003, the National Quality Forum (NQF) published *Safe Practices for Better Healthcare*, a report documenting 30 NQF-endorsed practices that should be used universally to reduce the risk of harm resulting from processes, systems, or environments of care.¹

In December 2003, NQF initiated a project as a follow-up to this report. Under a grant from The Commonwealth Fund, the project's goal was to identify strategies for accelerating widespread adoption of the NQF-endorsed voluntary consensus standard for informed consent, Safe Practice 10. Safe Practice 10 stood out among the 30 practices because of its cross-cutting relevance across clinical areas, its focus on patient-centered care, and its importance to patients who are particularly vulnerable to receiving poor-quality care and to being exposed to medical errors because of communication barriers. These patients often are those with limited health literacy, which includes both those with limited English proficiency (LEP) and native English speakers who have difficulty understanding healthcare terms and concepts.

Safe Practice 10¹

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

Additional Specifications

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

Given the broad scope of informed consent issues, the project focused specifically on the use of Safe Practice 10 for invasive, non-investigational, non-emergent procedures, in order to allow a focused evaluation of its use in a few discrete settings. The project also sought to evaluate the particular communication and informed consent issues for patients with limited health literacy.

The overall process for the project entailed the following:

- comprehensive assessments, including site visits, of the experiences of three “early-adopter” hospitals that had implemented Safe Practice 10 in order to identify major successes and challenges;
- evaluation of the implementation of Safe Practice 10 at one “pilot-adopter” hospital to examine “real-time” processes and issues in implementing the practice;
- phone interviews with healthcare professionals at “non-adopter” hospitals that did not use Safe Practice 10 routinely to identify the major barriers to broader implementation of the practice and to develop strategies to overcome those challenges; and

* NQF-endorsed Safe Practice 2 defines these “high-risk” procedures as 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 [$<1,500\text{g}$], those that are premature [<32 weeks gestation], or those that involve correctable major congenital anomalies).

- a multistakeholder workshop, held in September 2004, to review an analytical case study of preliminary findings and to develop additional recommendations about how to accelerate widespread adoption of Safe Practice 10 by U.S. healthcare providers.

This report contains a synthesis of the key barriers encountered and lessons learned by providers that adopted Safe Practice 10, including detailed evaluations of the experiences and perspectives of the early adopters, pilot adopter, and non-adopters. The report is designed to provide an overview of the major issues involved in providing informed consent for all patients, particularly those with limited health literacy. Its intended audience is all healthcare professionals who provide, administer, or manage healthcare, as well as researchers, policymakers, and others dedicated to improving quality. A separate publication, *Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals*, provides a concrete tool for assisting healthcare administrators, providers, interpreters, and others in implementing and using Safe Practice 10.

During the course of this project, a number of important issues surfaced as major priorities for improving informed consent, including filling in gaps in the informed consent processes at U.S. healthcare facilities, developing strategies to improve awareness of and communication with patients with limited health literacy, and implementing strategies to facilitate broader adoption of Safe Practice 10 by other providers. The key findings are as follows:

1. **Organizational Culture and Provider Buy-in.** Leaders at all levels within healthcare facilities must improve organizational culture and awareness in order to achieve greater provider buy-in for the use of Safe Practice 10. Such efforts should include provider education on the importance of adequate communication and informed consent, particularly for populations with limited health literacy.
2. **The Extent of Limited Health Literacy.** A major educational campaign should be undertaken to raise provider awareness about the extent of limited health literacy and to promote use of practices such as “teach back” for all patients.
3. **Training Providers About Informed Consent.** A standardized approach to educating providers about the informed consent process in general and Safe Practice 10 in particular should be utilized within healthcare facilities, and resources must be dedicated to ongoing provider education within these facilities in order to ensure that the improvements are sustained over the long term.
4. **Quality of Informed Consent Forms.** Healthcare facilities should improve their consent forms to be more reader friendly, simple, and useful to patients, particularly those with limited health literacy, while also educating providers about the central role of verbal discussion and involvement of interpreters (when needed) in the informed consent process.
5. **Use for Verification Versus Comprehension.** Efforts to implement Safe Practice 10 should include information about its usefulness in patient safety and general education, but also should emphasize its goal of ensuring broader patient comprehension through the informed consent process.

Additional guidance should be included in the user's guide to ensure that providers use the practice in a way that meets its stated goal.

6. **Level of Implementation.** Healthcare professionals should approach implementation of Safe Practice 10 based on consideration of the most appropriate, feasible, and effective strategy within their facilities. Initial use of "teach back" and other aspects of Safe Practice 10 as part of a pilot project within a limited setting may be useful in order to increase provider buy-in and facilitate future implementation more broadly across a facility.
7. **Costs and Benefits.** The successes of adopter hospitals and other evidence supporting use of "teach back" should be disseminated broadly to other providers in order to increase their willingness to implement Safe Practice 10.
8. **Provider and Non-Provider Roles.** Hospital leaders should clarify the roles of the individuals who participate in the informed consent process and should require all those who are involved to be responsible for ensuring adequate communication and patient understanding. Informed consent, however, is ultimately the responsibility of the physician, and this concept must be reinforced, although other professionals may play a role in promoting understanding.
9. **Compliance and Measurement of Patient Understanding.** Performance measures should be developed and applied to assess the level of patient understanding in the informed consent process and in general, including the degree to which patients are able to recount critical information.

10. **Volume-Outcome Disclosure for High-Risk Surgery.** Additional guidance should be developed to define what volume-outcome disclosure for high-risk surgery entails and to explain its importance to physicians, particularly surgeons. This information should explain why NQF endorsed this disclosure as a national voluntary consensus standard.

Efforts to change provider practice at any healthcare organization often will be met with some initial resistance. Still, although there are many barriers to adopting Safe Practice 10, the successes of adopter hospitals clearly demonstrate that effective strategies are available to overcome these barriers. More importantly, the overall value of using Safe Practice 10 has been shown to be well worth the effort needed to change provider practice.

Informed consent is a core component of quality healthcare. Patients who are well informed are more satisfied with their care, more trusting of their providers, and more able to make decisions that reflect their personal preferences and values. Effective communication between providers and patients is central to informed consent, and Safe Practice 10 provides an important, evidence-based, feasible, and usable approach that all providers can use to enhance the communication process in their larger quest to improve quality for all patients.

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Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy

Introduction

Ensuring that patients understand and consent to the healthcare interventions they receive is a basic component of patient safety. When consent is not fully informed, patients cannot fully participate in shared decisionmaking. Furthermore, when patients do not understand what is to be done to them, medical errors can result (including but not limited to wrong-site surgery, incorrect medication prescriptions, or severe or life-threatening reactions). Indeed, the consensus definition of surgery that is the “wrong” procedure or that is performed on the “wrong” site of the body is a procedure that is “not consistent with the documented informed consent for that patient.”²

Regrettably, the reality of everyday healthcare is that informed consent often is seen as simply a burdensome administrative practice that involves obtaining a signature on a form for the legal protection of physicians and institutions. Fully informed consent appears to be an unusual phenomenon, occurring in only 9 percent of clinical decisions in one large outpatient study.³ Studies show that after agreeing to or receiving care, 18 to 45 percent of patients are unable to recall the major risks of surgery,^{4,5,6} many cannot answer basic questions about the services or procedures they agreed to receive,^{7,8,9} 44 percent do not know the exact nature of their operation,¹⁰ and most do not understand (60 percent)¹¹ or read (60 to 69 percent)^{6,9} the information contained in informed consent forms, despite signing them.

Informed consent forms pose a particular problem for patients who have difficulty reading and understanding written information. In one study of informed consent for surgery and other procedures, the mean educational grade level required to understand consent forms was 12.6—that is, some college.¹² Even the small proportion of consent forms that are written at a lower grade level may well be inaccessible to many people. Based on the 1992 National Adult Literacy Survey, approximately 40 to 44 million people in the United States are functionally illiterate, and another 50 million people have marginal literacy skills. Furthermore, patients’ “functional health literacy,”¹³ resulting from a lack of familiarity with healthcare terms and phrases, may be much worse than their general literacy; the Institute of Medicine estimates that 90 million (47 percent) of U.S. adults have limited health literacy.¹⁴

The majority of American adults with limited health literacy are native-born, Caucasian English speakers. However, the ability of a patient with limited literacy to give fully informed consent to a procedure is compounded if the patient has limited English proficiency (LEP). In the largest study of functional health literacy conducted in the United States, a majority (60 percent) of patients at two public hospitals could not understand the standard consent form. Of English-speaking patients, 35 percent had inadequate or marginal functional health literacy, and of Spanish-speaking patients, 62 percent had those levels of limited health literacy.¹⁵ Those with limited literacy can be found among all races, ethnicities, genders, ages, and socioeconomic levels, but health literacy tends to be lower for those with LEP, cognitive impairments, learning disabilities, and/or low educational attainment, and among the poor, elderly, and minorities.¹⁴ Thus, many—if not most—patients with limited literacy and LEP who undergo surgical procedures have little understanding about the risks or alternative options, and even less opportunity to intervene if an obvious error is about to occur.

There is evidence, however, that this problem can be successfully addressed. A comprehensive literature review of informed consent in the general patient population found strong evidence that strategies that involved active verbal

engagement of patients in the process of informed consent will improve patients' attitudes toward informed consent and their recall and understanding of what they consented to receive.¹⁶ Patients who are asked to recount, also known as “teach back,” “repeat back,” or the “show me” technique, have greater recall and comprehension of risks and benefits of surgical procedures than those who are not asked to recount;⁷ and one study found that three times as many patients could recall this information after surgery if asked for “teach back” before the procedure than if they were not.¹⁷ Asking patients to “teach back” information to demonstrate their level of understanding is a widely recommended practice for effectively communicating with patients with limited literacy,^{18,19,20,21,22,23,24} because it increases patient retention, gives providers a gauge of how well patients understand information, and actively involves patients in their own healthcare. Simplification of informed consent forms to the fifth-grade reading level or lower also would increase understanding and recall of information about medical procedures for patients across all levels of health literacy.^{18,25,26,27}

Project Overview

In May 2003, the National Quality Forum (NQF) achieved consensus on a standardized set of evidence-based practices that would improve patient safety if universally implemented in applicable healthcare settings. The final set of 30 safe

practices was endorsed after 2 years of extensive examination and debate about underused patient safety practices by more than 150 organizations and national associations from across the healthcare enterprise, including patient and consumer groups; employers and business coalitions; health professionals, providers, and health plans and their associations; research institutions; and quality improvement organizations. Safe Practice 10 specifically addresses the need for active involvement in informed consent, including the underlying components that pertain to the specific needs of patients with limited health literacy, defined as those with LEP and those with difficulty understanding healthcare phrases and concepts (which includes but is not limited to those with limited literacy).

Safe Practice 10: An NQF-Endorsed Voluntary Consensus Standard

Safe Practice 10

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

Additional Specifications

- Use informed consent forms written in simple sentences and in the primary language of the patient.
- Engage the patient in a dialogue about the nature and scope of the procedure covered by the consent form.
- Provide an interpreter or reader to assist non-English-speaking patients, visually or hearing-impaired patients, and patients with limited literacy.

** Referred to as “teach back” in this project report.

- Convey the higher risk associated with suboptimal volumes for select high-risk surgeries and procedures as specified in [Safe] Practice 2.***

Safety Objective for Safe Practice 10

Ensure that patients or legal surrogates understand the proposed treatment and its potential complications.

Applicable Clinical Care Settings

All care settings.

The inclusion of Safe Practice 10 in the NQF consensus set of safe practices reflects the fact that it was reviewed, discussed, and formally voted upon by 155 national and regional healthcare stakeholder organizations, and it underscores the fact that this practice is widely recognized as important in reducing the risk of harm resulting from processes, systems, or environments of care. Despite the broad agreement on the importance of this practice, however, few healthcare organizations have implemented it, and no information or guidance has existed on how to do so. Thus, the goals of this project were to identify key lessons learned by providers that had implemented Safe Practice 10, determine the major barriers to implementation for others, and develop concrete guidance in the form of a user's guide for healthcare professionals in order to broadly accelerate the adoption of Safe Practice 10 on a national level.

Study Method

The project was guided by a Technical Advisory Panel (appendix A), informed by site visits and interviews (appendices B, C, and D), and further expanded upon at an invitational workshop (appendices A and E). The four major elements of the project were as follows:

1. **Early-Adopter Hospitals.** In order to learn from the experiences of a few early adopters, NQF identified and conducted comprehensive assessments of three selected healthcare providers that already had implemented Safe Practice 10. NQF used both a written self-assessment instrument and a site visit to interview hospital personnel involved in the informed consent process. The information derived from these evaluations formed the core background material for the project. The early adopters' experiences were crucial to learning about a) what was needed to successfully implement Safe Practice 10 at a healthcare organization; b) the major benefits and burdens; c) any unique or unanticipated issues associated with using the practice; and d) key lessons for other institutions that may wish to adopt the practice.

The three participating hospitals met the criteria of having implemented, at a minimum, the "teach back" component of Safe Practice 10 as a routine practice for informed consent or for related components of the surgical preparation process; they also had racially and ethnically diverse patient populations

*** The NQF-endorsed Safe Practice 2 defines these "high risk" procedures as 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 [$<1,500\text{g}$], those that are premature [<32 weeks gestation], or those that involve correctable major congenital anomalies).

and/or a large proportion of patients with limited health literacy. The early-adopter hospitals were:

- **Sherman Hospital.** Located in Elgin, Illinois, a small urban/rural setting within 70 miles of Chicago, this 350-bed, standalone, community hospital has a patient population that is 26 percent Hispanic/Latino (many of whom have LEP), a figure that is much higher than the estimated overall 14 percent of the U.S. population that is Hispanic/Latino.²⁸⁾
- **Shriners Hospitals for Children-Los Angeles.** Located in downtown Los Angeles, California, a major urban area, this 60-bed facility is a specialty orthopedic and burn reconstruction hospital for pediatric patients funded by the Shriners philanthropic organization, and all services are provided free of charge. At Shriners, 60 percent of patients speak Spanish as their primary language; a number of patients are also referred from Korea. Many patients are believed to have limited literacy and low levels of educational attainment. Clear communication by providers is a high priority given the nature of the patient population.
- **University of Virginia Health System (UVA).** Located in Charlottesville, Virginia, a small urban/rural setting within 70 miles of the state capital and 100 miles from Washington, DC, this 550-bed hospital is a major academic teaching facility. At UVA, 11 percent of patients in the immediate geographic service area are Hispanic/Latino, and 17 percent are immigrants or refugees. Based on one internal estimate, 64 percent of its adult surgical patients had a health literacy barrier (including LEP), with 31 percent of all of the hospital's patients functionally illiterate. Another study at the hospital showed that based on the use of a standard literacy test, 11 percent of its patients had the lowest level of literacy, compared with 4 percent nationally.

2. **Pilot-Adopter Hospital – San Francisco General Hospital (SFGH) Medical Center.** One hospital initiated a pilot project during the course of the study to test the implementation of Safe Practice 10 within a limited setting. NQF conducted a focused evaluation of SFGH's initial implementation experiences, which provided an invaluable, "real-time" opportunity to learn about the major barriers encountered in the process of planning, initiating, and using the practice.

SFGH is a comprehensive, acute care facility located in a major urban area and is a publicly owned teaching hospital with 500 acute care beds. The hospital's patient population is about 25 percent Caucasian, 22 percent African American, 21 percent Asian/Pacific Islander, 30 percent Hispanic/Latino, and 3 percent of another race/ethnicity. English is the primary language for 70 percent of the hospital's patients, while 14 percent speak Spanish as their primary language, 10 percent speak an Asian language, and 6 percent speak another foreign language. Given the low socioeconomic status of the hospital's population, health literacy levels are known to be low, and clear communication is a high priority for providers at SFGH.

3. **Non-Adopter Healthcare Organizations.** NQF staff conducted structured telephone interviews with healthcare professionals (including providers, administrators, and others) at organizations that had not formally implemented the NQF-endorsed practice for informed consent ("non-adopters"), in order to hear their perspectives on the practice, perceived barriers to implementation, and possible opportunities that could facilitate broader adoption of Safe Practice 10.
4. **Workshop.** In September 2004, NQF held a multistakeholder workshop to discuss preliminary findings from the early-adopter, pilot-adopter, and non-adopter healthcare organizations, to expand upon the key lessons learned, and to provide additional recommendations for promoting widespread adoption of Safe Practice 10 by U.S. healthcare providers.

Project Outcomes

The project resulted in two publications—this report and a user's guide for healthcare professionals, which includes an instructional card designed for provider reference in using Safe Practice 10 on a daily basis.

- **Project Report.** This report synthesizes the key barriers encountered and lessons learned in implementing Safe Practice 10 and presents recommendations for successfully implementing Safe Practice 10 and improving informed consent in general. Detailed case studies of the experiences of early adopters and the pilot adopter, feedback from the non-adopter interviews, and a synthesis of the workshop discussions and recommendations are contained in the appendixes of this report.

- **User's Guide.** A separate publication, *Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals*,²⁹ was produced to complement this report and provide a specific, focused tool to assist providers and administrators in implementing and using Safe Practice 10. It includes a reference card, *A Provider's Guide to Informed Consent*, designed to assist providers in using Safe Practice 10 on a daily basis.

Using Safe Practice 10: Four Hospitals' Experiences

Adoption of Safe Practice 10 at a healthcare organization consists of the implementation of the practice as a standard policy/procedure across a department (or the organization) and the use of the practice on a day-to-day basis by healthcare providers. Although Safe Practice 10 contains five specific components, the main “teach back” component of the practice was the primary target of evaluation for the project and was its most widely used component at each of the four adopter hospitals. As summarized in this section, the processes for implementing Safe Practice 10 at the early-adopter and pilot-adopter hospitals – and the strategies that providers at those hospitals used in asking for patient “teach back” during the informed consent discussion – illustrate models that may be useful for other hospitals seeking to adopt Safe Practice 10.

Overview of Adopter Hospitals' Implementation and Use of “Teach Back”

In all four hospitals, asking patients to teach back information related to their procedures was seen as a basic, required step in the process of care in the main departments studied, although it was not formalized in written policy, except at SFGH. Instead, adopter hospitals identified leadership, peer reinforcement, and ongoing staff training as the primary mechanisms accounting for the routine use of “teach back.”

None of the adopter hospitals used the exact, complete practice specified by NQF in Safe Practice 10; at the time of the study, NQF was unable to identify any hospitals that had been true “early adopters” of the NQF-endorsed Safe Practice 10, although some reported plans for implementing the practice in the future. However, the “teach back” practice had been in place at the early-adopter hospitals before publication of *Safe Practices for Better Healthcare*, and similarities with Safe Practice 10 were considered to be sufficiently comparable for the purposes of this project. The evaluations focused primarily on adopter hospitals' use of the “teach back” aspect of Safe Practice 10. The specific “teach back” practice used in each hospital is summarized in table 1 and described in detail in appendix B and appendix C.

Table 1 – Summary of Adopter Hospitals’ Implementation and Use of “Teach Back”

COMPONENT OF “TEACH BACK” ADOPTION	EARLY ADOPTERS			PILOT ADOPTER
	Sherman Hospital	Shriners Hospitals	UVA	SFGH
Time of adoption	2001	1994 or earlier	1998 (setting 1) 2004 (setting 2)	2001 (informal) 2004 (formal)
Reason for adoption	Part of a broader hospital patient safety effort to prevent wrong surgical site/procedure errors	“Teach back” has been part of the standard procedure for at least 10 years; exact origin is unknown.	Cost and staff time for delayed/cancelled surgeries resulting from inadequate patient understanding	Informal adoption in 2001 to increase the rate of patient return for pre-operative visits; formal adoption in 2004 for NQF project evaluation
Setting(s) where “teach back” is used	1. Pre-admission testing encounter 2. Ambulatory recovery center (surgical admission/discharge)	1. Peri-operative surgical admission suite 2. Pre-operative holding area	1. Pre-anesthesia evaluation and testing center (PETC) (setting 1) 2. Surgery clinics (setting 2)	1. Initial clinic visit 2. Pre-operative visit 3. Surgery admission
Individuals using “teach back”	Nurses Interpreters (ad hoc)	Nurses Interpreters (ad hoc)	Nurses Surgeons Anesthesiologists	Nurses Physicians
Process for educating providers and promoting use	Part of general initiation of all new staff to the unit on standard procedures; ongoing peer reinforcement	Ongoing peer education and reinforcement	“Teach back” called for by PETC medical director; ongoing education and reinforcement by peers, PETC director, surgical chair, and peri-operative manager	Staff meetings, broad educational efforts, leadership reinforcement, nurse reminders to physicians
Sample question used in asking for “teach back”	“For patient safety, please tell us in your own words what you’re here for.”	“What are you here for today?”	“Can you tell me why you’re here and what you need to do before surgery?”	“Explain to me why you think you need this operation and what the risks are.”
Documentation/application of patient response to “teach back”	Patient’s response is checked against the consent form and surgery schedule for consistency	Patient’s response is recorded directly on the surgical admission chart and checked against the surgery schedule and other forms for consistency	Information is repeated and clarified until patient shows adequate understanding and/or ability to “teach back;” providers document patients with difficulty teaching back, so that surgical staff can ensure that patients adhered to instructions	Informal – not documented; physician called if patients need more information Formal – box on consent form physicians must check to confirm patients recounted key information

Sherman Hospital

“Teach back” is performed in the preadmission testing encounter and upon admission to the holding area for surgery.

As part of a larger hospital effort to promote surgical safety and prevent wrong-site/procedure errors, Sherman Hospital initiated a repeat-back process in 2001. It is used routinely in three areas, with a deliberate redundancy built in to improve the likelihood that patients are truly informed prior to surgery:

1. In the encounter conducted by the pre-admission testing department, nurses read to patients the procedure listed on the surgery schedule and ask, “is this the procedure you understand that you will be having?” and “can you tell us why you will be coming to the hospital?” Patient responses are recorded on the admission form and are checked for consistency against other notes in the patient record. To demonstrate further understanding, patients also often are asked to answer additional questions, such as, “do you understand what’s going to be performed?”
2. Upon admission to the holding area on the day of surgery, nurses ask patients, “for patient safety, could you please tell us in your own words what are you here for today?” Patients are primarily asked to recount the correct site and procedure compared with what is indicated on the surgical schedule.
3. In the holding room, operating room nurses meet patients and ask them, “what procedure are you having done today?”

“Teach back” also is sometimes used to educate patients about their discharge instructions. Hospital staff provided the following sample phrase for use in this scenario:

I know I’ve just given you lots of information to share with the people who will be taking care of you at home. Since it is very important for them to also be clear on how you need to prepare for this procedure, and any restrictions or care you might need afterwards, could you please ‘teach back’ to me what I just shared, as if I were your spouse/caregiver at home?

Although “teach back” is not specifically a required practice for interpreters at Sherman Hospital, interpreters are empowered to be advocates for patients and to intervene

if it appears that providers are not communicating clearly to patients. Interpreters also are required to sign informed consent forms, after reading the form to patients, to attest that they provided interpretation for the encounter – thereby creating an additional mechanism to monitor whether patients with LEP were informed. Hospital staff provided the following sample phrase that interpreters might use in asking patients to recount:

I know you just received a lot of information. I want to make sure that I was clear in interpreting all the information you just received. For me to know if I did my job properly, could you please repeat back to me the information you just received, mentioning what, why, where, when, who, and how [the procedure] will be done?

The patient's response would be interpreted to the provider, who could then clarify any misunderstanding.

Shriners Hospitals for Children-Los Angeles

“Teach back” is used at various points in the pre-operative process.

Shriners Hospitals has been using the “teach back” practice for more than 10 years. Current staff members were unable to report specifically what prompted its implementation. Practices such as “teach back” generally are welcomed by Shriners providers, who serve an indigent population that is primarily LEP (often with no English language skills at all). “Teach back” helps providers communicate and gauge patients' understanding of the complex procedures performed and is used throughout the pre-operative surgical preparation process:

1. Upon admission to the peri-operative services unit, where patients are admitted prior to surgery, nurses ask patients about the nature of their medical condition and the procedure to be performed, using questions such as, “what are you here for today?” or “what kind of procedure are you having?” during the initial assessment. Patient responses are recorded on the assessment form and checked for consistency against the surgical booking record.

2. On admission to the pre-operative holding area to prepare patients for surgery, nurses again ask patients to state the procedure to be performed.
3. In the pre-operative holding area, when nurses retrieve patients for surgery, “teach back” is done again as a final safety check (for patients who are not yet sedated/heavily medicated).

Because Shriners is a children’s hospital, the patient’s parent or legal surrogate is usually the individual involved in “teach back” (pediatric patients are not legally authorized to provide consent under California law). Providers at Shriners, however, do involve patients in the discussion to the extent possible, particularly older children.

University of Virginia Health System

“Teach back” is done in the PETC, where patients receive comprehensive presurgical instructions and information, and it was recently implemented in the surgery clinics as part of the informed consent process.

At UVA, “teach back” was implemented in 1998 specifically in response to high rates of delays, cancellations, and “no shows” for surgery. The delays and re-scheduling were costly, given the wasted staff time that resulted. Hospital staff determined that the incidents often resulted from lack of patient understanding about the basic information and instructions they needed to follow prior to surgery (e.g., logistics of the registration and admission process, food/drink/medication discontinuation instructions). Today, UVA uses “teach back” in several areas:

1. In the PETC, patients are asked to recount all key information in their own words, particularly when instructions are complicated or patients show a lack of understanding. The baseline information patients are asked to recount includes the type of operation and its risks, benefits, and alternatives; instructions for medication discontinuation; food and drink restrictions before surgery; and other logistical information.
2. “Teach back” is again used when nurses call patients the day before surgery to confirm the time of the procedure; the particular focus at this stage is presurgical instructions, but nurses also confirm the patient’s understanding of the procedure.
3. As a final patient safety step prior to entering the operating room, nurses ask patients what they are there for and their understanding of what will be done.

During the course of the study, UVA was in the process of implementing “teach back” more broadly across the facility, and had recently implemented “teach back” for the surgery clinics as part of the presurgical informed consent discussion between physicians and patients. The provider participating in the informed consent discussion was required to have the patient repeat back the operation, risks, benefits and alternatives, and the recounted information—in the patient’s words—is documented in the medical chart. However, a more detailed evaluation of “teach back” implementation in the surgery clinics was not possible at the time of the site visit.

San Francisco General Hospital

“Teach back” has been done for three years in the elective surgery department, and successful “teach back” must now be documented on the consent form before surgery can proceed.

In 2001, “teach back” was initiated at SFGH as an informal, but routine, practice conducted by nurses in the elective surgery clinic. However, to demonstrate what was needed to adopt “teach back” as a formal policy, SFGH initiated a pilot project with NQF’s support in March 2004. Over the course of five months, hospital staff from various departments and review committees planned these formal changes to the informed consent policy. The procedural change in the informed consent process and form was launched in August 2004, with the implementation of the following major modifications: 1) use of “teach back” by physicians during the informed consent discussion and 2) documentation on a modified consent form that patients were able to repeat back information. Before implementation of the pilot project, use of “teach back” was not known to be common or routine by many physicians. “Teach back” now is used throughout the care process by both nurses and physicians:

1. At the initial clinic visit, after patients meet with surgeons to discuss their diagnoses and options for surgery, “teach back” is used by nurses when scheduling patients for their pre-operative visits. Nurses ensure that patients understand the information about their diagnosis and the surgical options, and they ensure that patients have made an affirmative

decision to pursue the surgery. The origins of “teach back” in this setting stemmed from the clinic’s nursing staff, who were able to link a high patient no-show rate for the pre-operative visit to lack of understanding.

2. At the pre-operative visit, which typically occurs about one week before surgery, patients provide their medical history and receive a physical examination, sign informed consent forms, and receive instructions for surgical preparation. Nurses ask patients for “teach back” at the end of these visits, a practice that was adopted informally in 2001, as with the initial clinic visit.

With the pilot project’s procedural change, attending physicians must request patient “teach back” during this visit before obtaining the patient’s signature on the consent form. After this process, nurses check again that patients can recount information in the consent form, asking them to describe information such as the nature, site/side, and major risks of the surgery. The level of detail that patients must recount is not specified, but the nurse is responsible for ensuring that patients demonstrate adequate understanding. A physician is called for additional explanation if a patient cannot adequately recount all key information to the nurse’s satisfaction.

3. On the day of surgery, patients again are asked by surgery department nurses to state what procedure they are to receive. Any indication of a lack of understanding results in a call to the attending physician to clarify information. This practice has been in use for approximately three years.

Formal Versus Informal Implementation

The adopters' experiences showcase four scenarios in which informal use of "teach back" by nurses is successful as a routine procedure. Nursing staff were educated on the need to use this practice through a variety of techniques, including new employee orientation by the department's administrative or medical director, in-service education, peer reinforcement, grand rounds, and e-mail.

SFGH is the only hospital in this study to require a formal change on the informed consent form in adopting Safe Practice 10, and several levels of review and approval were required to approve the change. Nevertheless, the protocol was implemented in less than six months. The steps required at SFGH for formal adoption were the provision of support or approval by the:

- hospital ethics committee, which must review all informed consent process-related changes;
- patient education committee, which includes health educators, specialty nurses, and others, and which has a particular interest and expertise in developing effective communication-related initiatives;
- quality management department, which oversees initiatives such as the pilot project and which designs and conducts performance monitoring and evaluation activities to measure the effects of the changes;
- risk management department, which must review changes to the informed consent process, particularly in the forms and the documentation procedures, in order to ensure provider legal protections are not compromised;
- hospital forms committee, which must approve changes to all forms, such as the informed consent form; and
- elective surgical department leaders – the chief of surgery and nurse manager – who must show support for such a change so that it will be used by other providers in the department, and who are ultimately responsible for educating and enforcing the use of the practice by providers in the department.

In addition, initiation and coordination of all the activities required a champion of the change, which at this hospital was a physician in a non-surgical department with a strong interest in the “teach back” practice and patient communication generally.

In contrast to informal adoption of “teach back” by nursing staff, formal adoption required a significant time commitment on the part of a number of hospital staff members involved in the pilot project. And although informal adoption may be quicker and easier than formal adoption, adoption of “teach back” as a formal practice could help promote compliance and increase provider knowledge of patient understanding issues, thus improving the quality of care overall. Formal use also could ensure that all patients are asked for “teach back,” because informal use presents a risk that the practice could become ad hoc and used only at the provider’s discretion. Overall, the challenges involved with formal adoption are as follows:

- **Levels of approval.** Within a department or hospital wide, it is likely that the approval of several institutional committees will be necessary.
- **Diversity of informed consent processes.** The variation in how informed consent occurs in different departments (e.g., for non-elective and emergency surgeries) presents a challenge in implementing a single informed consent practice facility wide. For example, patients undergoing elective procedures have more time to engage in discussion and absorb information than patients in other departments, such as the intensive care unit, who have only a few days or less to discuss and learn about their procedures. Patient comprehension was perceived to be lower in situations such as intensive care and emergent care, when there was less time available. Moreover, the dynamics of decision-making for inpatients compared to those in emergent care are markedly different.
- **Provider education.** The task of educating nurses, staff physicians, and residents – who rotate in and out of teaching hospitals every few months – is more challenging on a facility level than it is on a department level.

Additional Specifications of Safe Practice 10

The four additional specifications for Safe Practice 10 are common components of any well-designed informed consent process, and adopter hospitals reported following most of these additional specifications, with a few exceptions:

- **Using consent forms written in simple sentences and in the patient's primary language.** Consent forms were written in simple sentences at Shriners Hospitals and SFGH (estimated 6th-grade or lower reading level), but written at higher reading levels at Sherman Hospital (12th grade) and UVA (15th grade). Forms were available in the most common foreign languages for UVA and SFGH patients. Sherman specifically did not make the forms available in Spanish, in order to ensure that interpreters were called to interpret the verbal discussion that should accompany the form's signing.
- **Engaging patients in a dialogue.** All hospitals engage patients in a dialogue about the information described in consent forms, although the quality of these discussions was reported as varying among individual providers, departments (with the departments using "teach back" often cited as the best in doing this), and situations (e.g., elective versus emergency procedures).
- **Providing interpreters and readers.** Interpreters were available at all four hospitals, and staff were available to assist patients with reading and writing if it was clearly needed – for example, for illiterate patients who requested assistance, although not for situations in which patients' limited literacy was unknown.
- **Disclosing the higher risk of adverse outcomes based on provider volume of selected surgeries.** At UVA, physicians provided information about surgical volume only if asked by patients, and departmental web sites offered some public information about surgeons' volumes. Sherman Hospital did not use a different approach for informed consent for high-risk procedures associated with a volume-outcome relationship and does not confirm any instances of this information being disclosed as described in the specification. SFGH staff reported that some clinicians took extra precautions to ensure that patients understand the nature, risks, and benefits of higher-risk procedures, but it was unknown how consistent this was with Safe Practice 10. Shriners Hospitals did not perform any of the surgeries specified.

Adopter Hospitals' Success Stories: Benefits of Safe Practice 10

Both patients and providers benefit from clear communication. Adopter hospitals' successes in adopting "teach back" demonstrate that the practice is feasible, usable, effective, and meaningful to patients and providers. Adopter hospitals experienced some challenges in implementing and using Safe Practice 10, and their strategies for overcoming these challenges are described in a later section. This section describes the visible payoffs of using "teach back" and success stories as reported by staff at adopter hospitals. Specifically, five benefits drawn directly from the adopter hospitals were identified:

- ensuring medication safety,
- correcting misperceptions and promoting informed decisionmaking,
- avoiding surgical errors,
- promoting a culture of quality, safety, and patient-centeredness, and
- cost savings/the business case.

Ensuring Medication Safety

One patient's planned course of anesthesia would have resulted in a deadly complication, because the patient was taking a new, different medication, rather than the more common one for his disease that his physician had assumed he was using. Because "teach back" was used as part of the presurgical evaluation process at UVA, the patient had an additional opportunity to state the specific medications he was taking, which allowed providers to avoid an interaction with the planned course of anesthesia that otherwise may have been fatal. UVA staff reported several other examples in which medication interactions were caught only when patients were asked for "teach back," including one instance in which a patient's Coumadin use was disclosed; serious bleeding problems during surgery may have been avoided because of this patient safety catch.

For a diabetic patient at UVA who was expected to be non-adherent with pre-operative insulin discontinuation instructions (because of the patient's difficulty in accurately teaching back instructions), providers added notes to the patient's chart as red flags for surgical staff to check that his blood sugar would be at an acceptable level prior to surgery.

Accordingly, surgical staff checked the patient's blood sugar and found it to be dangerously high on the day of surgery, and they were able to take appropriate actions to ensure that he was stable before the procedure was performed.

Correcting Misperceptions and Promoting Informed Decisionmaking

Patients who are not well informed about the risks, benefits, alternatives, and reasons for surgery may be "no shows" or choose not to receive needed care simply because of poor communication, thus putting their health at risk. SFGH nurses reported that before adopting "teach back," patients often would miss their pre-operative evaluation visit, but reappear months later with a more serious, urgent condition because of the delayed care. This occurred presumably because patients did not receive enough information during the earlier encounter to convince them that the elective surgeries were important for their health.

Nurses initially attempted to address the issue of missed appointments by spending more time talking to patients, although they did not use "teach back" in this process; they found these additional efforts to be ineffective. Only when nursing staff asked patients to recount information did the "no-show rate" drop noticeably, because asking patients to recount the information provided a more interactive, concrete mechanism through which the nurses could know that the patients understood the relevant diagnoses, why surgery was important to resolve the problems, and

what the implications of not undergoing surgery could be. Although SFGH did not have specific data about the business case for “teach back,” that case clearly could be made, given the staff time and costs that were associated with re-scheduling and following up on missed pre-operative evaluation appointments.

Shriners Hospitals staff also reported that with elective procedures, particularly those performed at Shriners (burn reconstruction and orthopedic procedures), it was particularly important to ensure that patients’ expectations of the benefits of surgery did not exceed the anticipated outcomes. Staff reported that sometimes patients were disappointed after receiving surgery because they misunderstood the limitations of the procedures.

Sherman Hospital staff reported that a Spanish-speaking woman walked out of the hospital just before undergoing surgery when providers finally communicated clearly to her – and she was able to teach back – that the procedure she was about to undergo, tubal ligation, was a permanent sterilization technique; she previously believed it was only a temporary method of birth control. Use of “teach back” can help providers and patients reach a common understanding about a procedure and ensure that any such misperceptions are clarified prior to the procedure.

Avoiding Surgical Errors

Patients who are fully informed about their care can prevent medical errors and patient safety errors such as wrong-site surgery. Ensuring that patients are fully informed is particularly important for those with LEP, who have greater difficulty in intervening to correct healthcare providers. Staff at Sherman and Shriners Hospitals reported various instances in which patients verbalized information about the side/laterality or name of the procedure to be performed that conflicted with information contained elsewhere in the patient’s chart – which then generated additional checks to verify information about the procedure and clarify any misunderstandings for the medical team or patient. Verifying basic information through “teach back” is a particularly important step to take for those with limited health literacy.

Promoting a Culture of Quality, Safety, and Patient-Centeredness

Using “teach back” allowed nurses at UVA to discover inconsistencies in other areas of the care process, because they reported instances in which other units had given patients conflicting or inaccurate directions about pre-operative steps – only adding to patient confusion. “Teach back” allowed UVA to catch such inconsistencies and to monitor the quality of care internally.

The providers and departments who used “teach back” routinely at the adopter hospitals were widely recognized by their peers and by administrators with “cross-cutting” exposure as having the most well-informed patients, compared to other departments that did not use “teach back” in the informed consent process. Furthermore, in all of the adopter hospitals, “teach back” was used at several points in the process – by nurses, interpreters, and physicians. Given that patient education, informed consent, safety, and quality all should be ongoing processes, rather than discrete events or the responsibility of a single individual, this approach promoted a culture of quality, safety, and patient-centeredness.

Cost Savings: The Business Case

A convincing business case for the use of “teach back” emerged at UVA, when it was discovered in 1998 that more than 95 percent of surgery appointments that were cancelled or delayed were attributed to patient misunderstanding of presurgical preparation instructions (e.g., food/drink or medication discontinuation). The cost of delay was estimated to be \$56/minute in 1998, and it was estimated at \$70/minute in 2004, given wasted staff time, preparation of equipment, and other issues that resulted from delays and cancellations. With 8 percent of surgical visits resulting in delays or cancellations, the cost implications of poor provider communication and patient misunderstanding became clear and tangible. Approximately four months after adopting “teach back” within the PETC department at UVA, which sees approximately 80 to 100 patients/day, the surgery cancellation/delay rate dropped to 0.8 percent of visits, resulting in a major time and resource savings to the hospital.

Perceived Barriers and Potential Solutions to Implementation and Use

Professionals at the non-adopting health-care organizations raised a number of important issues about the major barriers to adopting Safe Practice 10 at their organizations. Adopter hospitals reported many successes and agreed that “teach back,” once implemented, had proven to be an invaluable practice for patient safety and quality, making some of the non-adopters’ concerns seemingly based more on belief than reality. Although many of the barriers to adoption that were raised by non-adopters were indeed encountered by adopters, they ultimately were able to use various strategies to overcome these challenges.

Provider Time to Ask for “Teach Back”

In busy hospital environments, where the providers who would be responsible for using “teach back” are stretched for time, having to ask patients to recount all the information from informed consent discussions was perceived as burdensome and time consuming, with one interviewed non-adopter estimating it could take up to 30 additional minutes to get successful “teach back” from patients. The time burden on providers in asking for “teach back” was one of the most commonly cited barriers to adoption of Safe Practice 10. In reality, providers at adopter hospitals reported that the time burden of using “teach back” was:

- greater initially, due to the learning curve for providers in developing the communication skills needed to be comfortable in asking patients for “teach back,” but ultimately not noticeable to nurses once the practice had become customary and engraved in their standard processes;
- typically a practice that took less than one minute to complete, although the encounter took longer if an interpreter was needed (arguably, however, improving communication for patients with LEP will require more time in any case). Also, one empirical study reported that encounters that included assessments of patients’ recall or comprehension were no longer than those without them;²²
- not a factor in the overall patient load handled within a department; UVA’s busy PETC clinic still was able to manage the same number of patients every day after the adoption of “teach back;”
- an improvement in efficiency rather than a time burden overall, given the time savings in other areas of the process (e.g., avoiding cancelled or delayed appointments); and
- worth the additional time needed to get patients to successfully “teach back,” given a provider’s professional and ethical obligation to communicate clearly to patients.

Physician Buy-in

The actual “teach back” practice was being used by all nurses and some interpreters at the three early-adopter hospitals, but there were only rare examples of physicians at those hospitals using “teach back.” Although early-adopter hospitals reported

some resistance from nurses during the initial implementation of the practice, staff later reported that getting buy-in from physicians was and would continue to be one of the most significant barriers – a finding that non-adopters echoed. Physician resistance to using “teach back” was attributed to several factors, which, if successfully addressed, could help improve their buy-in:

- **Perception that all patients understand.** At hospitals with a known population of patients at high risk of limited health literacy (e.g., those serving large numbers of LEP patients or public hospitals serving those with socioeconomic challenges), providers may be more aware that some patients will not understand basic information. However, the prevalent attitude among physicians is that most English-speaking patients understand the information conveyed to them and that patients who do not ask questions are fully informed; in fact, the lack of dialogue often is because the patients are intimidated or too poorly informed to know what to ask. In interviews with non-adopters, a number of healthcare providers reported that limited literacy was “not a problem” in their patient populations, or that information “should be really clear,” and certainty that “all patients understand 100 percent of what is said to them.” Given the vast literature documenting the extent of limited health literacy, this is highly unlikely to be true. Adopter hospitals recommended educating all hospital staff about the extent of limited health literacy and training providers to operate on the assumption that no patient understands all of the information that is provided to him or her.
- **Perception of lack of evidence demonstrating the benefit of “teach back.”** Physicians respond to evidence. Reporting data that demonstrate how “teach back” improves quality and safety – through reports of adopters’ successes and the scientific literature – is an important way to improve physician buy-in, according to non-adopters. Accordingly, the user’s guide for health-care professionals documents these benefits and presents a consistent body of evidence supporting the effectiveness of “teach back.”
- **Physician cultures and attitudes toward patient involvement.** Buy-in by some physicians may be harder to achieve than by others, and this will depend both on individual personalities and the nature of the environment. Several individuals commented that surgeons were likely to oppose using “teach back,” because of their busy schedules, limited time for discussion, and the possibility that their professional culture placed less importance on lengthy physician-patient discussions. Although this certainly reflects a larger problem involving physician culture and attitudes, education about the extent of limited health literacy and the evidence base for “teach back” may help convince these physicians to change their practice patterns. Leadership support, the involvement of a clinical “champion” of the practice, and policy requirements that physicians engage in practices such as “teach back” also are important in addressing this barrier.
- **Discomfort in asking patients to recount information.** Not surprisingly, asking for “teach back” in ways that are condescending, or in ways that make it appear that providers do not know the reason patients are receiving care, will

quickly result in negative patient responses and provider unwillingness to continue using the practice. Healthcare professionals who do not know how to ask for “teach back” effectively should be educated in what to do and what not to do. Asking “why are you here?” was reported to be an undesirable way of asking patients to state procedures to be performed, for example. Nurses at adopter hospitals suggested using phrases such as, “in your own words, can you tell me what will be done, so I can be sure we have the same understanding?” and emphasizing to patients that the question is asked as part of a safety check. Personnel from all early-adopter hospitals reported that reinforcing the message to patients that “teach back” was needed to ensure safety and adequate understanding was critical to successful patient and provider acceptance of the practice.

Simplifying and Translating Informed Consent Forms

Simplifying informed consent forms to ensure that patients understand the terminology and that the content is meaningful and useful for patient education often is an ongoing struggle for healthcare professionals and facilities. The challenge of representing all the needed legal concepts for physician protection in a way that is comprehensible to patients has become one of the most common struggles in informed consent process reform. Most consent forms are too complex for the majority of patients, the quality of information in them is highly variable, and the form often is too generic to provide useful information for patient education purposes. Although adopter hospitals also struggled with this issue, some individuals noted that the majority of medical malpractice cases are related to inadequate informed consent and that signed consent forms—particularly those that patients can demonstrate they cannot understand—are not sufficient to protect physicians in court. In fact, 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.^{14,30,31}

Federal law requires that all hospitals that receive federal funds provide translated informed consent forms to patients in languages spoken by a specific proportion or number of a

hospital's patient population.³² However, not all hospitals comply with this requirement, and the quality of translated materials may be questionable, at best. Adopter hospitals recommended strategies such as placing the English and translated versions side-by-side so that providers and patients would be viewing the same form; including interpreter attestation on consent forms regarding the adequacy of the translation; and documenting the type of interpretation provided (e.g., those provided by untrained hospital staff versus those provided by authorized interpreters).

Timing of Informed Consent

Although consent forms often are signed just prior to the surgery, “informed consent” — that is, the discussion about the procedure — should be done well in advance so that patients do not feel rushed into a decision. “Teach back” used early in the informed consent process can be a meaningful way to ensure understanding and promote active patient participation. When used just prior to surgery, however, it serves the purpose of confirming decisions that have already been made and avoiding surgical errors — rather than promoting patient choice or understanding. At each of the adopter hospitals, “teach back” was used at various points in the process both to promote understanding and to avoid medical errors.

Defining Adequate “Teach Back”

Particularly for procedures with highly technical concepts, “teach back” raised some issues for all adopter hospitals because the information that patients must be able to recount in order to demonstrate understanding was not specifically defined. Providers reported the following scenarios, which required some level of subjective judgment to determine whether patients truly understood the necessary information:

- **Patient's answer was too complex.** When asked to recount information about the procedure, the patient stated, “I'm here for a coronary artery bypass graft surgery.” Whether the patient understood the risk associated with that or what the terminology meant was unknown. Staff at adopter hospitals reported that asking patients to describe

the procedure “in their own words,” as they would describe it to a family member, was helpful in these situations.

- **Patient’s answer was too simple.** When asked to recount information about the procedure, the patient stated, “I’m here to have an operation on my heart.” Whether the patient understood the risk associated with the procedure, what the procedure was, and whether he or she cared about the nuances of the procedure were key issues, and providers spent additional time in discussion or used their judgment in these scenarios regarding what level of “teach back” was sufficient and appropriate.
- **Patient was unable or unwilling to recount.** The patient was too stressed or emotional to recount, or was unable/unwilling to do so. Although “teach back,” like any other communication practice, should not be enforced so rigidly that it makes patients uncomfortable (particularly for sensitive situations, such as those involving patients with diverse cultural values), providers should attempt the practice and find alternate ways to ensure that informed decisionmaking occurs based on what is appropriate for the situation.

Interpreter, Nurse, and Physician Roles in Using “Teach Back”

One issue in most hospitals’ informed consent processes involved knowing who should ask for “teach back” or use other similar practices. Informed consent is an ongoing process that all providers (and interpreters) should be committed to providing to patients; to be fully effective, it should be used whenever it is appropriate.

Interpreters face the challenge of ensuring that patients understand information and of providing subjective interpretation for both the physician and patient. However, although Sherman Hospital’s interpreters were empowered to serve as patient advocates and to intervene when patients appeared to need clarification, staff at other adopter hospitals thought this could generate tensions between interpreters and providers. One non-adopter reported that interpreters were required to be advocates for communication in one facility – that is, they would ensure that both the provider and patient had a clear understanding. Hospitals should clearly define who should be involved in which aspects of informed consent, and they should ensure that physicians ultimately are held responsible for ensuring patient understanding, although other healthcare professionals also should play a role.

Patient Attitudes About Informed Consent

Patient attitudes and cultural values about informed consent and physician authority presented multiple barriers to the entire informed consent process, including the “teach back” component. Patients with strong deference to physician decision-making authority simply did not see surgery and its risks as a matter of their own choice. This issue frequently was seen in some groups of patients with diverse cultural backgrounds. Nurses at all adopter hospitals also reported that patients often were intimidated by physicians and waited until physicians left the room to ask nurses questions about procedures – questions

that often required the physician to answer. Although providers should engage patients in discussions to the extent appropriate, they also should give all patients the opportunity to engage in their healthcare decisions without making undue assumptions.

Competing Hospital Priorities for Improvement

When asked to name their facilities' priorities for improvement, individuals at non-adopter hospitals rarely cited informed consent, although some did name patient safety. Safe Practice 10 relates to issues that are much broader than informed consent, however, with implications for professional, ethical, and legal obligations, compliance with accreditation standards and federal regulations, efficiency and cost, and equitable treatment for patients with LEP. Initiatives to improve the informed consent process must be presented to hospital leaders and providers in a way that links them to existing hospital priorities.

Process for Initial Implementation and Long-Term Sustainability

Formal adoption of Safe Practice 10, as demonstrated by SFGH, was a time-intensive process that involved several levels of review and/or approval by various committees and leaders. Although the burden of implementing this practice is not trivial, if it becomes a priority to hospital leaders and staff, it clearly can successfully be adopted in a matter of about three months.

The need to educate providers about Safe Practice 10 also was cited as a major barrier to adoption, and particularly to adoption on a broad level at a large facility with a high turnover of medical staff. Sustained efforts with adequate resources, especially for ongoing education, must be in place to support changes to a facility's informed consent process, because "quick fixes" will not be sustained.

Compliance and Monitoring

Non-adopters commented that any policy changes must be implemented along with a specific mechanism for ensuring compliance and monitoring, so that the changes can be assessed for their impact on patient care. Many individuals were concerned that the greatest burden would fall not in requiring the use of the practice itself, but in the time that would be required performing chart audits or patient surveys to determine how well providers were complying. Questions about how compliance should be measured also were raised. Adopter hospitals reported that they lacked mechanisms for documenting and monitoring overall rates of patient comprehension; arguably, few well-established measures are available for this concept. On the other hand, many hospitals do not routinely monitor or assess compliance for various other institutional policies.

"Teach back" clearly can be successfully documented and monitored for compliance, however, as occurred in SFGH's case. Moreover, without specific mechanisms for monitoring compliance, deviations from standard procedures can occur frequently. Sherman Hospital staff reported witnessing

instances in which, in order to save time, information that should have been elicited from a patient's response or a physician's written order (i.e., the procedure to be received) was instead provided by nurses based on the surgery schedule or on other information that was already in the patient's chart. At UVA, the use of "teach back" during phone calls to notify patients of surgery times also did not occur as routinely as expected, because patients who did not answer the phone were simply left messages specifying the surgery time. Similarly, "teach back" did not always occur when nurses were able to contact the patient directly, but did not have time to engage in any real discussion with the patient (other than confirming the surgery time) because they had too many other calls to make. Such deviations from the informed consent process were frequent because of time constraints and because of a desire by some providers to speed up the process.

Key Findings and Recommendations

Over the course of the project, a wealth of information was generated about how informed consent was conducted at various hospitals, what providers' experiences were in applying various aspects of Safe Practice 10 in everyday practice, and what the perceived barriers and potential solutions were to facilitating broader adoption of Safe Practice 10 across the United States. In general, the informed consent process in use at U.S. healthcare facilities is woefully in need of major improvements in the communication that occurs between providers and patients and in order to ensure that informed patient decisionmaking occurs. The specific findings regarding how to accomplish these goals with respect to the use of Safe Practice 10 are summarized below, along with recommendations for action.

- 1. Organizational Culture and Provider Buy-in.** Provider attitudes toward the importance of informed consent, active patient involvement in decisionmaking, adequate communication, the extent of limited health literacy, the benefits of using "teach back," and the need for additional steps to ensure patient understanding and safety are important barriers to increased buy-in and willingness to

adopt the practice among individual providers and within healthcare organizations.

Recommendation: Leaders at all levels within healthcare facilities must develop a strategy aimed at improving organizational culture and awareness in order to achieve greater provider buy-in for the use of Safe Practice 10. Such efforts should include provider education on the importance of adequate communication and informed consent, particularly for populations with limited health literacy.

- 2. The Extent of Limited Health Literacy.** The needs of English-speaking patients with limited literacy and other challenges in understanding health information often were not noticed by providers, even in adopter hospitals. These providers generally were unaware of the prevalence of limited health literacy among patients and the potential scale of the comprehension problems in their English-speaking patients. Patients with LEP also may have issues in understanding, especially when providers wrongly believe that these patients understand English to a sufficient degree that an interpreter is not needed. Both within individual healthcare facilities and across the U.S. healthcare system, the healthcare information comprehension needs of patients are often overlooked.

Recommendation: A major educational campaign should be undertaken to raise provider awareness about the extent of limited health literacy and to promote the use of practices such as “teach back” for all patients.

- 3. Training Providers About Informed Consent.** No structured, formalized approaches have existed for educating providers about how to perform “teach back.” Provider education was named as one of the most critical needs for successful implementation of this practice. On a broader level, the quality of informed consent discussions is known to be problematic at most hospitals, and providers could be educated on the use of “teach back” in conjunction with much-needed training on how to communicate more clearly with patients about their care.

Recommendation: A standardized approach to educating providers about the informed consent process in general and Safe Practice 10 in particular should be utilized within healthcare facilities, and resources must be dedicated to ongoing provider education within these facilities in order to ensure that the improvements are sustained over the long term.

4. **Quality of Informed Consent Forms.**

Many consent forms are not written at a level that much of the U.S. adult population can read, often because of the legal terminology that is embedded in them, or they are otherwise too intimidating for patients or do not serve any meaningful patient education function. The content of the form often is ambiguous and vague and does not provide much useful information for patients. Consent forms should be written at or below the fifth-grade reading level, and they should be available in the patient's primary language. The quality and usefulness of the information in these forms also must be improved to ensure that they serve a purpose other than liability protection for physicians. Appropriately developed and translated forms, however, should not be construed as replacements for providers holding discussions with patients (with interpreters, when needed).

Recommendation: Healthcare facilities should improve their consent forms to be more reader friendly, simple, and useful to patients, particularly those with limited health literacy, while also educating providers about the central role of verbal discussion and the involvement of interpreters (when needed) in the informed consent process.

5. **Use for Verification Versus**

Comprehension. Providers varied in their interpretation of the goal of "teach back": It was construed as needed to verify basic information, such as surgical site, to otherwise ensure patient safety (for uses beyond informed consent), to gauge the level of patient comprehension by identifying language/literacy barriers, and to enhance generally the communication process. Although asking patients to verbalize information about surgical

site is important for safety, and "teach back" can be used in general patient education, the stated objective of Safe Practice 10 is to promote broader patient understanding in informed consent; asking for "teach back" solely for verification of surgical site is insufficient to meet the goal of the practice.

Recommendation: Efforts to implement Safe Practice 10 should include information about its usefulness in patient safety and general education, but also should emphasize its goal of ensuring broader patient comprehension through the informed consent process. Additional guidance should be included in the user's guide to ensure that providers use the practice in a way that meets its stated goal.

6. **Level of Implementation.** Safe Practice 10 can be implemented at multiple levels: individual providers, departments, facilities, or health systems. Different issues arise regarding the feasibility, burden, and challenges of adopting Safe Practice 10 at each level. Multilevel approaches to adopting Safe Practice 10 are possible, and providers can overcome the challenges and burdens involved by considering the most effective and feasible strategy for implementing the practice in their systems of care.

Recommendation: Healthcare professionals should approach implementation of Safe Practice 10 based on consideration of the most appropriate, feasible, and effective strategy within their facilities. Initial use of "teach back" and other aspects of Safe Practice 10 as part of a pilot project within a limited setting may be useful in order to increase provider buy-in and facilitate future implementation more broadly across a facility.

7. **Costs and Benefits.** Non-adopting providers often perceived the costs and time burden involved in implementing “teach back” to be much higher than adopters perceived them to be, and many non-adopters questioned the value of the practice. The burden of implementation varies by facility and how the practice is implemented. However, those using the practice have found that the time burden involved is minimal and that the benefits far exceed the costs over the long run. Non-adopting providers must be persuaded that implementing the practice will result in overall improvements in time, efficiency, cost, quality, safety, and patient-centeredness, as demonstrated by adopters.

Recommendation: The successes of adopter hospitals and other evidence supporting the use of “teach back” should be disseminated broadly to other providers in order to increase their willingness to implement Safe Practice 10.

8. **Provider and Non-Provider Roles.** Physicians, nurses, and interpreters all were involved in “teach back” and other aspects of the informed consent process, which often resulted in blurred lines regarding who was ultimately responsible for ensuring patient understanding.

Recommendation: Hospital leaders should clarify the roles of the individuals who participate in the informed consent process and should require all those who are involved to be responsible for ensuring adequate communication and patient understanding. Informed consent, however, is ultimately the responsibility of the physician, and this concept must be reinforced, although other professionals may play a role in promoting understanding.

9. **Compliance and Measurement of Patient Understanding.** The degree to which providers performed “teach back” for all patients, as required by standard procedure, is largely unknown because of a lack of monitoring mechanisms. More broadly, the degree to which providers complied with professional, institutional, and legal requirements to clearly communicate and provide true “informed consent” is unknown, and few well-established measures exist to gauge how well patients understand this information. Although patient ability to “teach back” can be documented, it is only a partial indicator of the level of patient understanding.

Recommendation: Performance measures should be developed and applied to assess the level of patient understanding in the informed consent process and in general, including the degree to which patients are able to recount critical information.

10. **Volume-Outcome Disclosure for High-Risk Surgery.** Significant concern was raised about implementing this additional specification of Safe Practice 10, and many providers were confused about what performing this aspect of the practice entails. The increasing use of this practice by major groups, such as state medical regulatory boards and the Leapfrog Group, however, underscores the importance of this information to purchasers and consumers.

Recommendation: Additional guidance should be developed to define what volume-outcome disclosure for high-risk surgery entails and to explain its importance to physicians, particularly surgeons. This information should explain why NQF endorsed this disclosure as a national voluntary consensus standard.

Conclusion

Informed consent is a process that is rooted in effective communication between physicians and patients. Although informed consent is an ethical, professional, and legal duty of healthcare providers, it often is not given the attention it deserves. Today's healthcare delivery system is in need of major transformation in order to improve the quality of care, and until effective changes are made, patients who suffer from limited health literacy, including those with LEP, will be at a significant disadvantage. The potential consequences of continuing to neglect the needs of this important and growing segment of the population are tremendous: Quality, safety, and patient-centered care are at stake until improvements are made to the provider-patient communication process for informed consent and across the continuum of care.

Although healthcare facilities may face a number of barriers when considering the adoption of Safe Practice 10, these barriers can be overcome. The adopter hospitals described in this report all were dedicated to improving quality, safety, and patient-centeredness. Their successes in changing provider practice have demonstrated the invaluable benefits of Safe Practice 10—benefits that, in the long run, have far outweighed any initial doubts about whether it was worth the time and effort to make such a change. The NQF-endorsed Safe Practice 10 provides an important, evidence-based, feasible, and usable set of strategies that all providers should use in the informed consent communication process as an integral part of their larger commitment to improve care for all patients.

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NATIONAL QUALITY FORUM

Appendix A

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Appendix B

Case Study – Early-Adopter Hospitals and Self-Assessment Protocol

The major components of the case study consisted of identifying a group of early-adopter hospitals that met specific criteria, evaluating their use of Safe Practice 10 and related processes for informed consent, assessing their services for patients with limited literacy and limited English proficiency (LEP), and analyzing their experiences in order to identify models for success. The detailed findings from these evaluations are described in this appendix.

Identifying Early Adopters

National Quality Forum (NQF) staff sought the participation of three collaborating, “early-adopter” healthcare facilities, which were identified through communications with NQF Member organizations and through extensive outreach efforts to relevant experts. The basic criteria for participation as an early adopter were as follows:

- the facility served significant numbers of patients with LEP and/or limited literacy; and
- at a minimum, the main component of Safe Practice 10, which calls for patient “teach back” in informed consent, or a practice that was reasonably consistent with it, was:
 - in use at the facility;
 - applied systematically across a department as a policy or routine practice;
 - used in the patient care setting (i.e., non-investigational); and
 - used for non-emergent care related to surgical or other invasive procedures.

The three early adopter hospitals that met the criteria and were invited to participate were:

- Shriners Hospitals for Children-Los Angeles
- Sherman Hospital
- University of Virginia Health System (UVA)

Of note, despite outreach to a large number of healthcare providers and preliminary indications from at least 12 institutions and numerous other providers that they had implemented the practice, very few had actually adopted the practice as specified and within the limits of the study. Surprisingly, finding providers that had taken any additional measures to ensure patient understanding in informed consent by using practice(s) similar to the one endorsed by NQF in the “Safe Practices” report also proved very difficult. Results from the Leapfrog Group’s 2004 survey of nearly 900 hospitals indicated that 33 percent of hospitals reported that they were implementing informed consent process improvements that were generally related to the goals of Safe Practice 10, but the degree to which these hospitals were implementing procedures consistent with the specifications of the practice were largely unknown.*

Ultimately, the challenges confronted in recruitment provided lessons about the current state of the informed consent process and underscored the opportunities available to broaden the use of Safe

Practice 10 in today’s healthcare delivery environment. The most frequent reasons for exclusion from this study were as follows:

- **Competing priorities.** Providers had plans for implementing the practice, but were uncertain when and/or if implementation would occur, given competing priorities.
- **Research setting.** The practice was used in research settings, whereas this study focused on its use in patient care settings.
- **Other patient care settings.** Healthcare professionals who provided non-invasive care, which was outside the scope of the project, reported using “teach back” as a communication strategy—for example, in family practice, pediatrics, and psychiatry, and for general patient education.
- **Other practices.** Other providers used strategies that were related to, but not reasonably consistent with, the NQF-endorsed practice—for example, asking, “do you understand?” to ensure patient understanding, rather than using “teach back,” or asking patients to verify surgical site as a patient safety check rather than to ensure understanding.
- **Individual provider/ad hoc use of the practice.** A number of individual providers, both physicians and nurses, reported ad hoc use of “teach back” in informed consent and general patient communication, but the project required systematic use of the practice across the department or facility level as a formal policy or routine practice, so that a meaningful evaluation of the practice’s implementation could be conducted.

* Personal correspondence, Catherine Eikel, The Leapfrog Group, November 29, 2004.

Evaluation Process

With the invaluable assistance of a primary designee at each adopter hospital (appendix A), NQF staff conducted detailed evaluations of each hospital's informed consent processes and experience using the "teach back" practice. The evaluation process consisted of two components:

- **Written self-assessments.** NQF staff developed a written self-assessment instrument (figure 1), with the input of the project's Technical Advisory Panel and staff from the early-adopter hospitals. The self-assessments were completed by representatives from the early-adopter hospitals and included questions about the hospitals' general characteristics; patient populations; informed consent policies, processes, and procedures; experiences with using "teach back"; and mechanisms for addressing the needs of patients with LEP and limited literacy.
- **Site visits.** To gain a full perspective of how the informed consent process occurred at the early-adopter hospitals on a daily basis, NQF staff conducted two-day site visits in June 2004 to each hospital. During the visits, NQF staff met with numerous hospital personnel to discuss lessons they learned from using, administering, and/or implementing "teach back." In accordance with the study protocol, the site visits did not include patient contact or direct patient observation by NQF staff.

The hospital staff interviewed at each facility included physicians, nurses, and non-clinicians in leadership, administrative, and clinical care positions from departments such as pre- and postoperative general

surgery; neurosurgery; emergency; family medicine; anesthesiology; cultural competency/interpreter services; quality improvement; chaplaincy; ethics; medical forms/records; risk management/legal services; and patient education.

The diverse group of hospital staff interviewed revealed a wide range of perspectives and apparent differences in the organizational cultures of the three hospitals. Of note, even within each hospital, significant variation among staff perspectives often was the norm—both in individuals' personal philosophies about patient care and their style of practice relating to the same aspects of care, including the informed consent process. In some cases, practices that some staff thought were standardized within or across units/departments clearly were not. Participants uniformly noted that the self-assessment and site visit had proved very useful to them in reviewing their practices and policies and in helping them identify opportunities for improvement—even though they already were adopters and leaders in informed consent.

The Informed Consent Process

The following sections describe the early adopters' informed consent processes. Overall, the informed consent processes were generally similar among early-adopter hospitals and non-adopter hospitals. Given the ethical and legal evolution of informed consent in the United States (particularly the latter), this is not surprising. These similarities in process make a strong statement about the feasibility of implementing Safe Practice 10 at other hospitals as well.

General Overview

At all early-adopter hospitals, the primary discussion about the diagnosis, risks, benefits, alternatives, and expected outcomes of surgery occurred in the physician's office, generally during an outpatient encounter that occurred well before the date of surgery. The informed consent form usually was signed during a pre-operative history and physical examination, on the day of or the day before surgery. Additional checks existed to ensure that patients' questions were answered during the pre-operative process, and nurses in various pre-operative preparation departments were responsible for checking patient records to ensure that the consent form was signed properly, to ensure general patient understanding about the procedure, and to confirm basic information, such as the site and side of surgery. The overall informed consent processes at early-adopter hospitals reflected typical practices for most patients undergoing surgery at other hospitals, with the major difference being in the use of "teach back," which is discussed in depth in the body of this report.

Hospital Policies and Procedures

The formal processes for providing informed consent generally were similar among the early-adopter hospitals as well, as they had been developed to address legal, regulatory, and administrative demands.

- **Legislative requirements.** State legal regulations around informed consent were primarily focused on issues such as patients' decisionmaking authority and

capacity, and they only generally cited the need for physicians to communicate clearly; they did not address the degree of patient understanding that was needed. Legislative requirements were neither a barrier to nor a mechanism for encouraging adoption of Safe Practice 10.

- **Hospital policies.** Facility-wide policies at the early-adopter hospitals were in place to provide additional specificity around issues such as which procedures required consent and how to handle unique situations. They generally were developed to be consistent with legislative, accreditation, and other requirements. None of the early-adopter hospitals explicitly mentioned "teach back" in its policy documents—that is, the practice was in place as a result of routine process and/or a culture and was not formally codified.
- **Departmental processes.** Routine use of specific communication practices such as "teach back" occurred at the micro level (e.g., within a specific department) and generally occurred with much less formality and rigidity than would be present in macro-level policies (e.g., hospital-wide written policies, legislative requirements). Interdepartmental variations in how consent was obtained were common, based on the flow of care, the nature of procedures performed, and the relevant policies and requirements (e.g., informed consent was not required for minimally invasive procedures, such as central line catheters initiated in the intensive care unit). Departments with more time for patient discussion (e.g., those performing elective surgical procedures) generally were perceived by staff in other areas of the hospitals to "do informed consent better."

Staff attitudes in different departments at all three hospitals, however, demonstrated that some units took more responsibility and placed greater importance than others on both obtaining proper informed consent and engaging in effective patient communication. The departments with the most extensive processes for obtaining informed consent (e.g., those who used “teach back”) often were cited by their peers as the “best” in patient communication.

- **Forms.** The early-adopter hospitals used separate consent forms for surgery and anesthesia, general medical treatment, and specific services such as medical photography and blood transfusion. Sherman Hospital’s surgery consent forms were generalized, without information about the specific risks of the actual procedure to be performed, and UVA’s and Shriners Hospitals’ forms used generalized templates for surgical consent, with blanks that could be filled in with information about procedure-specific risks and other information. Proper completion of the forms constituted a patient signature, a physician signature (at two hospitals), a witness signature (at two hospitals—usually a staff nurse), and an authorized interpreter’s signature (at one hospital).
- **Staff roles.** The referring physician and operating surgeon were responsible for informed consent—generally defined by early adopters as a full discussion about the patient’s diagnosis, procedural risks and benefits, alternatives, and potential complications. The practice of documenting in the patient’s record that these discussions occurred, beyond having a signed consent form, however, was performed inconsistently within and among all three hospitals. Documentation about the patient’s level of understanding generally did not occur.

At all three hospitals, although the “true” informed consent discussion fell under the physicians’ purview, nurses were responsible for checking patient records to ensure that consent forms were signed properly and for ensuring that patients understood information about their diagnosis and procedure (although physicians often were required to provide the actual answers). Many nurses at the early-adopter hospitals reported that advocating for better patient understanding was a core function of their jobs, but they often did not feel empowered to do so, given the “power imbalance” between physicians and nurses in the department and/or at the facility.

- **Written aspects/documentation.** Early-adopter hospitals lacked processes for formally monitoring the level of patient understanding, because there was no requirement to specifically document that “teach back” had occurred; related indicators were documented, however. Shriners Hospitals used an admission form with a line reading “reason for hospitalization as stated by parent/patient,” based on patient responses. Sherman Hospital used a patient history form on which patients or nurses wrote the reason for the hospital stay, including a description of the illness, when it began, and current treatment. UVA recently changed a form to read, “is the patient’s understanding of the procedure consistent with the consent?” Previously the same question was worded to ask whether the patient’s procedure matched the consent, without reference to understanding. Such simple wording changes on routine assessment forms could be effective for prompting providers to ask patients to recount information.

- **Compliance, monitoring, and measurement.** Compliance with the use of “teach back” generally was believed by each facility to be near 100 percent within the applicable department/unit, but because this was not specifically documented, it could not be verified. The only monitoring or measurement for compliance consisted of formal chart audits, which verified that patients signed the consent forms, but not that they understood them. Indeed, Sherman Hospital found one instance in which a patient with LEP had signed a consent form with no interpreter present; this finding prompted the hospital to initiate a policy requiring authorized interpreters to sign consent forms attesting they had been present.

Measurement of the extent to which patients were adequately informed was indirect, with hospitals’ patient satisfaction surveys cited as the primary mechanism for obtaining such information. Early-adopter hospitals administered surveys asking patients to rate their care in areas such as, “explanation the physician gave you about what the surgery or procedure would be like” (before the surgery), and “information nurses gave you on the day of your procedure.” Improvements on their survey responses following implementation of “teach back” would make a strong case for providers to use the practice, given the importance of patient satisfaction to hospital administrators, providers, and the public. Surveys must be designed with the needs of patients with limited health literacy in mind, however, as some commercial surveys may be written at high reading levels and administered only in English.

Informed Consent for Populations with LEP

Early-adopter hospitals’ programs and services for populations with LEP generally were extensive, and some unique approaches to providing quality care for these patients were utilized that offer interesting models for other providers.

Interpreter Services

Early-adopter hospitals used a variety of services to meet the language needs of patients. Shriners Hospitals had many English-Spanish bilingual medical staff members, one of whom also served as a medical interpreter but with no formal training as such. Sherman Hospital primarily had trained, dedicated English-Spanish medical interpreters (8.6 full-time equivalents [FTEs]), including some that stayed within specific departments at assigned hours (e.g., the emergency department from 11:00 am to 11:30 pm), and providers called upon other authorized medical staff to interpret, if needed. UVA had English-Spanish medical interpreters (3.5 FTEs). Although dedicated medical staff interpreters generally were preferred, they were not always readily available (e.g., at certain hours), and other options also were used when necessary, including community volunteers (particularly for less common languages), hospital staff without formal training in medical interpretation, commercial translation telephone services, and patient family members (generally cited by facilities as a last resort).

The extent to which patients with LEP received adequate interpretation – for informed consent or for care in general – varied widely among the three sites. The same issues at these hospitals are likely to be problematic in most hospitals, and include the following:

- **Access to interpreters.** Professional staff interpreters with formal training in medical interpretation are considered to be the best option for communicating with patients with LEP, but they were available during limited hours (i.e., normal business hours on weekdays) at all hospitals, making the time of day or day of week for the medical encounter a factor in the quality of care for patients with LEP. Other options available after hours, such as commercial phone translation services, were considered a last-resort option for many staff, with some raising concerns that many providers were unaware of the availability of the system or how to use it.
- **Quality of interpreters.** Use of interpreters without formal medical training (e.g., medical staff with varying levels of fluency in a language, community volunteers) was an issue at all hospitals. Dedicated, in-house staff interpreters were available only for the Spanish language at all hospitals. Family members also were used to interpret when better options were unavailable; providers raised concerns that often it was apparent that these interpretations were biased.
- **Provider usage patterns.** Staff interpreters noted that some providers were simply more receptive to using interpreters than others, with notable variation occurring regarding which physicians or departments utilized their services. At Shriners

and Sherman Hospitals, some physicians reported that they preferred to use office staff or their own limited knowledge of a language to communicate in order to facilitate the encounter; others at these facilities noted that the wait time and delay in the arrival of staff interpreters was a barrier. Physicians also commented that the additional time required to communicate to patients during interpreted encounters was a burden and that using the “teach back” practice in these instances required more time.

Interpreter Roles in Informed Consent

Dedicated staff interpreters at the early-adopter hospitals were guided by codes of ethics and professional conduct to provide appropriate, objective medical interpretation, and their role in the informed consent discussion was primarily to provide direct interpretation between providers and patients. However, interpreters also were empowered to serve as patient advocates in the event that providers’ communication techniques clearly did not meet the needs of the patient. In one example at UVA, this role was utilized when a physician used a metaphor (“I’m sorry, but the cow is out of the barn”) to disclose a cancer diagnosis that clearly was not meaningful in the patient’s language. Nurses at UVA and Sherman Hospital agreed that, because of the presence of an additional patient advocate during interpreted encounters, their patients with LEP often received better communication during informed consent discussions when compared to their English-speaking counterparts.

At Sherman Hospital, interpreters routinely asked patients to confirm whether they understood or agreed with each point raised by providers during informed consent discussions. If patients responded negatively, or otherwise indicated a lack of understanding to interpreters or nurses, they were encouraged to refrain from signing the informed consent form and undergoing surgery until further discussion with their physicians. One provider, who served as an interpreter at Shriners Hospitals, reported using “teach back” routinely and noted that the practice was not being used by physicians, but rather that the interpreter was responsible for initiating the requests for patients to recount information.

Because “teach back” was not systematically or broadly used by physicians during the full informed consent discussion, the areas of the process with the heaviest interpreter involvement generally did not include the application of “teach back.” Some interpreters reported limited use of “teach back” to ensure patient understanding, but given their designated, objective role and duty to interpret providers’ words directly – without additional commentary or interference unless a clear need for clarification and advocacy arose – interpreters were limited in their ability to initiate requests for patients to recount information. Interpreters primarily relied on experience, intuition, and patient behavioral clues (e.g., body language) to detect whether patients had difficulty understanding, which required them to inform the physician that additional explanation was needed.

Translation of Informed Consent Forms

Although early-adopter hospitals had various educational and other patient materials available in multiple languages (primarily Spanish), somewhat surprisingly, all three hospitals deliberately had only English versions of the informed consent forms available at the time of the site visits. Staff at all three hospitals agreed that the critical issues for patients to understand were not written on informed consent forms, but were communicated verbally by physicians – with the form serving primarily to provide legal protection for the physician and hospital and not to promote patient understanding or provide information. Additionally, Shriners Hospitals did not use informed consent forms in non-English languages to ensure that physicians were able to understand the legal document they were signing, a strong statement about how the document was designed for physician liability protection and not for patient education.

Sherman Hospital chose not to have its informed consent forms available in foreign languages for a very different reason – to ensure that rather than simply being handed a form about their procedures, patients with LEP would have an interpreter present to read the English language form to them. The hospital’s procedures required that authorized interpreters read the entire consent form to patients and sign their names under the patients’ names, in order to ensure that patients with LEP had an authorized interpreter present during the informed consent discussion. One interpreter at Sherman Hospital estimated that in

approximately one-third of informed consent encounters, patients with LEP did seek additional clarification of information from the physician. UVA's informed consent form also included a line for interpreters to sign as witnesses to indicate they had provided translation for patients.

The notion that patients with LEP had information needs that could not be met simply by the provision of a translated informed consent form – which did not ensure that a properly interpreted discussion occurred – provides a potential model for other hospitals to use when considering how their processes can be re-engineered to compel appropriate use of interpreter services. Staff at Sherman Hospital reported initial resistance from nurses when the decision was made to not offer translated forms and instead to require the presence of interpreters, but they noted that such resistance decreased once nurses understood how it would ensure quality care for patients with LEP.

Informed Consent for Populations with Limited Literacy

For English-speaking patients with limited literacy, the fewest checks were in place to ensure adequate patient understanding. Moreover, physicians strongly believed that, unlike patients with LEP, most English-speaking patients did not have trouble comprehending information about their care. Studies consistently contradict this perception, however, as noted in the body of the report. Even physicians who believed patients understood information about their care and that patients

were adequately informed about their procedures acknowledged that it was difficult to know whether that was truly the case. Patients with limited literacy were acknowledged as being difficult to identify because they usually concealed their lack of understanding well. Providers also reported hesitation in using “teach back” to identify patients with limited literacy, for fear of talking down to and/or offending them.

Some physicians at Sherman and Shriners Hospitals said that most of their patients would be unable to teach back information from their discussions to a satisfactory degree, regardless of how much time was spent explaining. Because of the difficulties involved in identifying patients with limited literacy and physicians' perceptions about the extent of limited literacy, achieving informed consent appeared to be the most extremely problematic for these populations.

Readability of Written Materials

The informed consent forms were written at the 12th- and 15th-grade levels for Sherman Hospital and UVA, respectively, based on standardized readability assessments; they were estimated to be at the 6th-grade level for Shriners Hospitals, although readability had not been formally assessed there. The readability of the diverse group of patient educational and other written materials was highly variable and was not well assessed. The poor readability of consent forms was attributed, in part, to the same reasons that the forms often were not available in many foreign languages for patients with LEP – because

these forms generally did not contain much important information beyond what should be discussed verbally with patients; thus making them comprehensible was not a high priority.

Staff at all three hospitals reported that efforts by hospital personnel to simplify the reading levels of the forms often were met with great resistance from legal and risk-management staff; an obvious struggle occurred between legal staff, who wanted to include the detailed language necessary for liability protection, and hospital staff, who wanted to simplify the language to ensure greater understanding for patients.

Other Methods to Assess Understanding

Some tools were available by early-adopter hospitals to help providers identify patients with learning barriers or those who otherwise had difficulty understanding information. These tools included the following:

- **Surgery booking/educational record.** When scheduled for surgery at Shriners Hospitals, patients were given a form to complete that included statements such as, “I was given information on the following” and “I understand the following information,” related to diagnosis, type of surgery, benefits of surgery, possible complications, and other areas.
- **Learning assessment screening.** As part of the patient admission and discharge process, UVA providers completed a form that included a learning assessment screening, with spaces for providers to document patient language preference, ability to read/write, and preferred learning method.

- **Interdisciplinary patient/family educational record.** UVA and Sherman Hospital used forms at various points in the pre-operative process to assess patient understanding of the diagnosis/illness and procedures to be done, with spaces included that providers could use to document learning barriers (e.g., vision, hearing, educational, language), teaching methods or preferred learning styles (e.g., handout, translation, video), and patient responses (e.g., needs reinforcement/repetition, no interest in learning).

Observational Methods to Gauge Patient Understanding

Providers at all three hospitals frequently cited the use of several traditional (and often ineffective) methods for ensuring understanding, such as asking patients, “do you understand?” (which was known usually to elicit a “yes” response, regardless of the level of understanding) and “do you have any questions?” (which often elicited “no” responses from patients hesitant to ask questions). Other reported strategies for detecting limited literacy or confusion included using provider experience/intuition, determining the patient’s educational level, and observing patient facial expressions, gestures, body language, or inability to complete written forms.

Other Special Populations

Although this project focused on the challenges of informed consent and healthcare communication faced by patients with limited health literacy, including LEP, additional populations

also warrant special attention. During the course of this assessment, NQF and staff at all hospitals noted that efforts to improve informed consent more broadly should consider ways to ensure that the needs of these groups also are met.

- **Deaf/mute/hearing-impaired patients.** The unique needs of these patients present a major challenge to providers. Many patients who are deaf or mute have very low levels of literacy, in addition to requiring sign language-based communication, which is limited in its ability to fully convey complex medical terminology and procedural details.
- **Cognitively impaired patients.** The ability to demonstrate understanding about healthcare choices is seriously compromised in those with cognitive impairments, many of whom are elderly, and this can pose particular difficulties for providers who request that patients recount information.
- **Psychiatric patients.** A complex array of issues surrounds the provision of care for patients with psychiatric disorders because of their limited decisionmaking capacity. Informed consent policies for these patients are usually different than those for non-psychiatric patients, and the processes rely heavily upon hospital policies and state legislation around the rights of these patients.
- **Culturally diverse patients.** Hospitals with large international populations face additional challenges in delivering culturally competent care, which extends above and beyond language barriers. Early-adopter hospitals treated particularly diverse patient populations and reported that conflicting patient beliefs about healthcare presented challenges when applied against the traditional U.S. notions about informed consent.

Summary: Lessons Learned from Early-Adopter Hospitals

The experiences of early-adopter hospitals provided valuable lessons for other providers seeking to implement Safe Practice 10. It is important to note, however, that because none of the early adopter hospitals in this study had implemented the exact informed consent practice endorsed by NQF in *Safe Practices for Better Healthcare*, additional consideration of particular issues involved in using the specific NQF-endorsed practice is needed.

Implementing and Using “Teach Back”

Early-adopter hospitals’ challenges in implementing “teach back” and ensuring its ongoing, effective use provided valuable lessons about how other hospitals’ implementation efforts should be designed in order to be successful.

- **Education requirements.** Routine use of any new communication practice such as “teach back” requires initial and ongoing education for all hospital staff involved. At teaching hospitals, issues such as high staff turnover, a constant influx of new physicians, and the involvement of many different levels of medical staff (e.g., medical students, residents, attending physicians) in the communication and care processes make the task of provider education particularly demanding. “Teach back” was used systematically in only a few departments at the early-adopter hospitals, where educating and managing participating staff could be well controlled. The strategy for successfully implementing such a practice institution wide, even in the early-adopter hospitals, would need to be far more complex, however.

- **Standardizing provider practice.** None of the early-adopter hospitals specifically called for “teach back” in its formal, written organizational policies on informed consent, and deviations from practice were reported due to limited provider time. Despite this, “teach back” had become a routine part of the care process for some departments. Thus, it seems well within reach for similar departments in other institutions to implement “teach back.” Whether non-adopters can use the same techniques as those used by the early-adopter hospitals (i.e., education and peer reinforcement) is less clear. For example, additional levers, such as senior management leadership, clearly are important; the real-time implementation of SFGH is illustrative in this regard (appendix C). Other change levers—for example, hospital, legislative, or regulatory policy changes—that were not part of the case studies, also may be important.
- **Administration of the consent form.** The distinction between informed consent as a form and informed consent as a discussion is clear. Linking these two components more closely would provide an opportunity to ensure that the discussion occurs, given the monitoring and compliance mechanisms that are already in place to ensure that the forms are properly completed. The experience of reading through English forms with Spanish-speaking patients bears this out. Today, however, a major barrier exists to achieving this linkage, in part because physicians are responsible for the discussion and nurses are responsible for ensuring that the form is completed. If the same processes used to ensure that “consent was obtained” in the form/signature sense could be tied to additional processes to ensure that “the patient understood what was in the consent,” then the objectives of Safe Practice 10 would be better met.
- **Timing of informed consent and “teach back.”** Informed consent discussions that were held just prior to surgery and when additional time for patient questions could result in a delay in the surgery schedule were typically much shorter than those held in less rushed situations. “Teach back” at time-sensitive or high-pressure points in the care process was likely to be used primarily as a safety check for surgical site/side confirmation, rather than to ensure greater patient understanding of the procedure. Implementing “teach back” at points during the care process when adequate time for additional discussion is available is important in order to ensure that the underlying goal of Safe Practice 10 is met.
- **Defining adequate “teach back.”** “Teach back” was used largely by the early-adopter hospitals to confirm basic information about procedures. Even at these facilities, however, the sentiment was expressed that there is 1) a need for additional guidance to ensure that the practice is meaningful and achieves its desired purpose of engaging physicians and patients in a broader dialogue about patient care and 2) a need for a mechanism to assess its effectiveness. With respect to the former, more specific documentation of the discussion aspects of informed consent on both the consent form and in the patient chart would begin to address this problem. To evaluate adequacy, systematic examination of measures such as patient experience/satisfaction survey questions before and after implementation could prove to be informative.

- **Asking for “teach back.”** Educating providers about the best way to approach patients and ask for “teach back” is key to successful implementation of Safe Practice 10. A surprisingly strong and prevailing physician view, particularly at Sherman Hospital, was that many patients would be unable to teach back information from their discussions to a satisfactory degree, regardless of how much time the physician spent providing explanation. Before “teach back” can begin to be widely implemented even at these early-adopter facilities (let alone be successful), executive and clinical leadership that places a priority on patient-centered care and shared decisionmaking will be needed.
- **Burden of use.** Although many physicians at the early-adopter hospitals who did not use “teach back” perceived it to be too time consuming and burdensome, the nurses who actually performed “teach back” generally did not share this perception, because “teach back” was such a routine part of their daily practice. Initial implementation of the practice is likely to be the most time-consuming part of instituting “teach back,” but after the learning curve peaks, “teach back” clearly can become routine, and the time needed to use it diminishes. UVA had determined that the use of the practice decreased the overall burden on providers with respect to time and the resources wasted when surgeries were cancelled or delayed – which nearly always resulted when patients did not clearly understand information about their procedures or care. However, it must be noted that although overall using “teach back” may reduce time burden and costs in some areas, healthcare providers may find the additional communication step itself to be burdensome.

Caring for Populations with LEP and Limited Literacy

For patients who face communication challenges, both in English and non-English languages, surgery is a daunting process. Improving the informed consent process to ensure these patients are adequately informed is critical for a system to achieve equitable, high-quality care.

- **Better consent for patients with LEP.** Providers and interpreters at the early-adopter hospitals indicated that they believed that, when interpreter services were used optimally, patients with LEP often received better informed consent than English-proficient patients. Interpreters who act as advocates help patients receive high-quality care, not only because they assist with patients’ language needs, but because they are likely to be aware of patients’ cultural issues. However, the barriers to interpreter access and other challenges in caring for patients with LEP, even within these model hospitals, demonstrate the urgent need for stronger efforts to improve care for these populations.
- **Patients with limited literacy: the most vulnerable population.** Overall, patients with limited health literacy, particularly due to reasons other than LEP, appeared to be at the greatest risk for being inadequately informed because of a lack of provider awareness about the extent of limited health literacy and provider inability to gauge patient understanding. A widespread effort is needed to educate physicians about the prevalence of limited health literacy, as well as to provide tools to help them better care for these patients.

Broader Healthcare System Issues

The numerous challenges in implementing and using Safe Practice 10 at early-adopter hospitals were also representative of the broader priorities for reform in the U.S. healthcare system. Without a stronger dedication by providers and leaders to improve patient safety, equity, and quality, efforts to implement practices such as “teach back” are unlikely to succeed.

- **Organizational culture.** At each early-adopter hospital, the organizational culture of patient safety and provider commitment to ensuring patient understanding were generally strong, providing a supportive environment for practices such as “teach back.” At the same time, clear physician resistance was encountered in departments not implementing the practice at these hospitals. To successfully obtain physician buy-in for broader use of Safe Practice 10, hospitals must have a leadership and organizational culture that supports improvements

to the informed consent process with practices such as Safe Practice 10, that supports and rewards documentation of meaningful informed consent, and that supports and encourages measurement of success (or lack of success) in implementing the practice.

- **“Teach back” for all healthcare settings.** A sentinel department at each adopter hospital emerged as a leader in utilizing the “teach back” practice; generally this was the department that was viewed as having primary responsibility for ensuring that patients were informed before surgery. However, this responsibility should not be isolated within a single unit of any hospital; effective patient communication and informed consent should occur across the continuum of care. Safe Practice 10 is recommended for use in all healthcare settings, and a broader commitment to patient understanding on the part of all providers in the U.S. healthcare system, even within adopting hospitals, is critical in achieving high-quality care.

FIGURE 1. SELF-ASSESSMENT PROTOCOL FOR EARLY-ADOPTER HOSPITALS

PURPOSE

This assessment will evaluate the experiences of healthcare facilities that have implemented the NQF-endorsed practice, or a consistent practice, for informed consent on a systemic level for its general, limited-literacy, and limited English proficiency (LEP) populations. The assessment will focus on a specific department within the identified facility that performs informed consent related to the receipt of invasive procedures, and it seeks to evaluate: i) when the teach back practice was adopted; ii) ease of adoption; iii) how the facility assesses whether healthcare professionals utilize the practice; and iv) how facilities determine that patients understand the information and services they receive.

PROCESS

The assessment of your facility will be completed through two major processes: a written and on-site component. This document and your responses to it will constitute the written component; the site visits will be used to expand upon and obtain additional information around the answers provided in the written component. A general overview of the additional information NQF staff will be asking during the on-site visit during interviews with hospital staff is provided at the end of this document to assist you in preparation for the on-site component.

THE INFORMED CONSENT PRACTICE

As endorsed by NQF, the complete specifications for the practice under evaluation are:

Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.¹

Additional specifications:

- Use informed consent forms written in simple sentences and in the primary language of the patient.
- Engage the patient in a dialogue about the nature and scope of the procedure covered by the consent form.
- Provide an interpreter or reader to assist non-English-speaking patients, visually or hearing-impaired patients, and patients with limited literacy.
- Convey the higher risk associated with suboptimal volumes for select high-risk surgeries and procedures as specified in Practice 2.²

INSTRUCTIONS

Please complete all items to the best of your ability, with assistance from any relevant staff at your facility. Additional peer review and feedback on this self-assessment by others at your facility is strongly encouraged. Please note the differences between questions that should be answered at the facility level and the department level and also specify in your answers which level is being described whenever appropriate.

Following completion of the self-assessment, NQF staff will hold a site visit to your facility to follow up on the results of this assessment, obtain additional documentation and information, and interview key personnel at your facility. Thorough and timely completion of this self-assessment is critical to ensuring our site visit is productive and efficient.

¹National Quality Forum. *Safe Practices for Better Healthcare*. NQF: Washington, DC; 2003; 31-32.

²Ibid, 22-23. The "high-risk" procedures are defined as coronary artery bypass graft, coronary artery angioplasty, abdominal aortic aneurysm repair, pancreatectomy, and esophageal cancer surgery. Also included in Practice 2 are selected high-risk deliveries.

continued

USE OF INFORMATION

The detailed information you provide in this process will be used internally by NQF staff only and will be made available more broadly only at your discretion – i.e., this assessment itself will not be duplicated in the case study or project reports, but rather synthesized by NQF staff for review and discussion by other participants in the project. NQF recognizes that some of the requested information may originate from internal quality improvement efforts at your facility that you do not wish to share publicly; please do not allow this concern to restrict the information you provide to us during the assessment process. We will work closely with you to ensure that the nature and content of the information that is shared publicly about your facility are consistent with your preferences. The synthesized results of this self-assessment, findings from the site visit, and all other information obtained from relevant follow-up efforts may be included in the analytical case study, reviewed by the Technical Advisory Panel, presented at the workshop, and described in the final project report and user's guide.

As a collaborating provider on this project, your participation in these activities authorizes NQF to use and reproduce the information obtained in the manner described above; **you will have the opportunity to review the case study before its dissemination.** No individually identifiable patient information will be requested by NQF, nor should it be provided by the institution. Anonymized individual-specific examples that are useful to illustrate the institution's experience are appropriate and welcome.

You have been asked to participate in this study because you are one of the few “early adopters” of this specific practice in the U.S. healthcare system. Your commitment to ensuring adequate patient informed consent as a basic principle of quality healthcare establishes you as a leader in this area, and your candid and detailed response to this self-assessment is critical to meeting this project's goals. This self-assessment is NQF's first attempt to evaluate the success of one of its endorsed national voluntary consensus standards for healthcare quality, and, as such, many of the items included on this assessment may relate to areas that have not previously been evaluated at your facility. However, this is not only an opportunity to learn from past experiences, but also a way to set future quality improvement priorities for your facility. All the information you are able to provide will be valuable to other providers who are looking to your experiences as their model.

Thank you for your assistance in this project!

I. Basic Information *

PRIMARY CONTACT	Provide for the primary individual responsible for completing this assessment
Name Degree(s) Title Department Mailing address Phone Fax E-mail	
Role in informed consent process	Please explain the primary contact person's role in developing, administering, implementing, and/or assessing the informed consent process at your facility:
General Hospital Information Facility name Address Website address	
Department where the NQF practice is used (primary department under evaluation)	For the primary department within your facility that uses the NQF practice for informed consent which will be assessed in this study, indicate the Department name: Department address (if different than main facility address): Nature of the services/procedures performed in this department: Specific services/procedures for which the NQF practice is used in this department:
Other departments where the NQF practice is used	Indicate any other departments where the NQF practice is used at your facility (or indicate "none" if applicable):
Facility Management and Administration	For each individual below, please provide the requested information. If no individuals, or multiple individuals, exist for these roles, please indicate so and include all relevant names and contact information.
President/CEO	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Chief Operating Officer	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Chief Medical Director	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Director of department where NQF practice is used (list medical and administrative directors, if different)	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:

* Staff contact information shall not be reproduced or otherwise disseminated, but is sought only to permit follow-up inquiries from NQF project staff.

I. Basic Information * (continued)

PRIMARY CONTACT	Provide for the primary individual responsible for completing this assessment
Facility Management and Administration <i>(continued)</i> Director of quality improvement	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Director of risk management	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Director/lead staff for cultural competency initiatives	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Director/lead staff for language translation services	Name and degrees: Formal title (if different than indicated): Phone number: E-mail address: Role in informed consent process/policy:
Other – facility management and administration	List any other key individuals responsible for the development, administration, implementation, and/or assessment of the general informed consent process, both in direct patient care and policy setting for your facility (does not need to relate specifically to the NQF practice). Please list each individual separately. Name and degrees: Title: Phone number: E-mail address: Role in informed consent process:
Other – informed consent practice-specific personnel	In addition to the primary contact, list ALL the key individuals who will assist in providing the information for this self-assessment. This should include the individuals who carry out the NQF practice with patients on a day-to-day basis. Please list each individual separately. Name and degrees: Title: Phone number: E-mail address: Role in informed consent process:
Hospital Profile Year of inception Type of hospital Profit status Ownership	Please provide a brief description of the hospital's profile, or attach an annual report that contains this information.

* Staff contact information shall not be reproduced or otherwise disseminated, but is sought only to permit follow-up inquiries from NQF project staff.

I. Basic Information * (continued)

PRIMARY CONTACT	Provide for the primary individual responsible for completing this assessment	
Hospital Profile <i>(continued)</i> Major services provided Current JCAHO accreditation status Key hospital memberships/associations		
General Patient Demographics Average daily census Number of beds Annual admissions Annual procedure volume	For entire hospital/facility N/A	For department being assessed Indicate the volume for the specific procedure(s) for which the informed consent practice under evaluation is applied.
Race/ethnicity	Indicate % of patients in each racial/ethnic group; mark "unknown" if not known.**	[Answer only if known to be substantially different than at the hospital level.]
Data source for race/ethnicity		
Primary language	Indicate % of patients in each non-English language group; mark "unknown" if not known.**	

* Staff contact information shall not be reproduced or otherwise disseminated, but is sought only to permit follow-up inquiries from NQF project staff.

** Based on whatever classification system is used by the hospital/department (e.g., White, Black, Asian/Pacific Islander, etc., for race/ethnicity).

II. Target Population: Patients with Limited English Proficiency

a. Policies/programs

- What general policies, programs, processes, and services are in place at the facility to address the language needs of patients with LEP? Please include a description of the on-site and off-site (e.g., telephone) services available and when each is utilized.
- How are the needs of patients with LEP addressed in a typical encounter? How does the patient or hospital staff access/request these services, and how do hospital staff determine what type of interpreters are used?
- What kinds of interpreter staff are available on-site and by telephone, and how many are available (including FTE per language, if known)? What tasks are they expected to perform, how are they trained for this, and how does the facility/department ensure they are qualified to handle these tasks?
- Is there any specific training on the medical terminology used in the department? How does the facility/department ensure interpreters are truly able to translate the terminology contained in the consent?
- How does the facility or department address patients' variable levels of health literacy, given that some may be more able to understand the medical terminology than others (barring language issues)?
- What policies does the facility have in place specifically to address the federal regulations for language access?

b. Population assessment

- How does the hospital staff determine whether patients are sufficiently proficient in English to complete the informed consent process without an interpreter? Are there specific tools or scales that are used to determine this? If indirect/proxy indicators (e.g., race/ethnicity) are used to identify potential patients with LEP, please describe those.

c. Barriers/obstacles

- What are the major barriers or obstacles faced in addressing the needs of patients with LEP at the facility? What additional resources (e.g., funding, interpreter staff, medical staff time for additional discussion) are needed, and what is the extent of this burden? Is waiting time to receive interpreter services a barrier?
- Are there cultural issues in addition to language issues, and what procedures are used to handle these issues (e.g., the role of other family members in medical decisionmaking)? How does hospital staff handle difficult situations?

d. Informed consent for patients with LEP

- What steps have the facility AND department taken to translate their informed consent forms – in what languages are they available? Has the adequacy of the written translation been assessed and how?
 - How did the facility/department decide which languages should (and should not) be available, if a decision was made to translate forms in some languages but not others? What assessments were done to find out what the patients' languages needs were?
 - How are family members used in the informed consent process for interpretation, decisionmaking, and assisting in understanding? If family members are used in the process, what safeguards are in place to ensure the accuracy and completeness of the information conveyed (e.g., is a trained interpreter still involved)?
 - What assessment mechanisms are in place generally for ensuring the adequacy of interpretation in the informed consent process? How does the facility/department ensure patients are truly "getting the message"?
 - Does the informed consent process include a verbal discussion? Is there time provided for this discussion if the patient does not show full understanding, and who assists in answering questions?
 - In what other ways does the department's overall informed consent process ensure the needs of patients with LEP are addressed?
-

III. Target Population: Patients with Limited Literacy

a. Policies/programs

- What specific processes does the facility/department have in place to assist patients with limited literacy at the point of care? Who is responsible for carrying out these processes? Please also describe any training that the facility/department staff are given to sensitize them to literacy issues for patients who do not understand.
- Does the facility or department have an operational definition for a “low-literacy patient”? If so, what is it, and what special provisions are made for these patients?
- How does the facility or department identify patients who do not appear to understand the information in a typical encounter at the department under evaluation? What policies are in place to ensure all patients understand, and how does the facility/department know whether providers are following these steps to ensure understanding?

b. Population assessment

- Has the facility previously assessed the literacy levels of its overall patient population, or are there data on the literacy levels of the community served by the hospital? If so, what was the scale, classification, or rating system used to assess literacy levels (e.g., grade school reading level), and what were the results?

c. Barriers/obstacles

- What major barriers or obstacles are encountered in ensuring informed consent for patients with limited literacy, both by patients and for staff in caring for these patients?

d. Informed consent for patients with limited literacy

- What steps has the department/facility taken to simplify the reading level of the department’s informed consent forms? At what reading level is the department’s informed consent form written? How has this been assessed?
 - In what other ways does the department’s overall informed consent process ensure the needs of patients with limited literacy are addressed? Is there time provided for discussion if the patient does not show full understanding, and who assists in answering questions?
-

IV. Department's Informed Consent Practice

a. Comparison to NQF practice

- How does the department's informed consent practice relating to repeat back differ from the NQF-endorsed practice? Please provide a detailed comparison based on the full set of specifications for the NQF practice given on page 1.
-

b. General description of the informed consent process

- Please provide a full description of both the department and hospital's informed consent processes/policies, which includes the repeat back practice and all other related aspects of informed consent. Attach supporting information that includes a copy of the hospital and department's full informed consent policies, all relevant forms given to patients (including all informed consent forms, if there are different versions based on literacy level/language), and instructions for providers and administrative staff for obtaining informed consent. Please provide the information, as follows:
 - the individual(s)/team that are responsible for obtaining informed consent, with a full description of which individuals carry out which specific tasks (e.g., providing forms, initiating discussion, asking for repeat back, following up on questions), and who is responsible for what aspects of obtaining consent and repeat back;
 - what questions are asked/discussions are held;
 - when and where in the care process consent and repeat back are obtained, particularly relative to when the procedure is actually performed;
 - for what specific aspects of care consent and repeat back are obtained;
 - description of what constitutes whether the patient was sufficiently able to perform repeat back and steps taken when patients are unable to repeat back;
 - how consent and repeat back are documented (e.g., electronic/medical record);
 - what forms are reviewed and signed by patients; and
 - any other relevant information.
-

c. Current implementation experiences

- How does the department ensure the overall informed consent process has occurred as specified in its policy? What indicators/measurements of adherence to the policy does the department have, or how does it plan to measure this? Is there a place to document how the informed consent was delivered (e.g., translated document, use of an interpreter/type of interpreter used) and whether it was successful?
 - How does the department ensure that the repeat back aspect of informed consent is occurring as specified in its policy? What indicators/measurements of adherence to the policy does the department have, or how does it plan to measure this? Is there a place to document whether repeat back took place, and whether it was successful?
 - Has the department determined the extent to which the needs of patients with limited literacy and patients with LEP are being met by the repeat back practice? If so, what were the results of these evaluations?
 - How are department staff trained to carry out the informed consent process, both generally and specifically for the repeat back aspect? Who is responsible for participating in discussions with the patient when repeat back is not successful?
 - How is the informed consent process typically carried out in the department, in comparison to how it is specified on paper? Are there some aspects of the process that may often be skipped or neglected, and what are they?
 - Are patients' decisionmaking/legal surrogates involved in the informed consent process; if so, when and how?
 - Does the department have specific mechanisms to account for cultural differences in the informed consent process, and if so, what are they?
 - For pediatric patients, are there differences in the department's approach to informed consent? If so, what are they?
-

d. Comparison to facility/other departments' policies/processes

- Other than the department under evaluation, is repeat back used more broadly across the facility where informed consent takes place, and where? If not, why is it limited to some departments, and what are the barriers to broader implementation of the practice across the facility? Are there other "best practices" to ensure informed consent in other departments, and what are they?
 - How does the informed consent process differ for departments that handle consent for the "high-risk" surgical procedures and other specified care, as defined in NQF-endorsed safe practice 2 (see footnote on page 1), as it relates to procedures or care that are not included in the department under evaluation? Is repeat back used in any of these departments?
-

IV. Department's Informed Consent Practice (continued)

e. Related quality improvement initiatives

- What related quality improvement initiatives does the hospital have – for informed consent, patient-physician communication, and/or the special needs of patients with limited literacy or patients with that LEP that were not described previously?
 - Does the hospital conduct a patient satisfaction survey, and if so, does that measure the informed consent process? Does it measure any other related aspects – i.e., satisfaction with interpreter services?
-

V. Assessment of Experiences

a. Past experiences

- How do the department and facility's current informed consent processes and policies compare to past versions? How have they changed, and what prompted them to change?
-

b. Initial implementation

- When was the repeat back aspect of your informed consent process first implemented? Who initiated the process, and what inspired adoption of the practice? Over what time period and how did it evolve to the current form (if it differs)?
 - Were there any specific strategies or actions taken to address the needs of patients with limited literacy and patients with LEP in using repeat back during your informed consent process, in addition to how the practice was generally implemented for all patients?
 - What new activities or processes had to be put in place to implement the repeat back practice that were not previously available, both generally and for populations with limited literacy/LEP?
-

c. Costs/benefits of implementing repeat back

- Does the overall process take more or less time now compared to informed consent without the repeat back aspect? How much more or less time does it take, and how is that measured? Did the use of repeat back, both generally or for patients with limited literacy/LEP, cause other changes in the department's informed consent process? What other costs/burdens have been added or reduced because of this practice?
 - Are there any plans to apply this practice more broadly to other departments at the facility? How, where, and when would this be done? Who is responsible for deciding?
-

On-Site Interviews: General Overview

This section contains an overview of some of the questions NQF staff will ask during the on-site interview and is included here for your preparation purposes. You do NOT need to answer these questions during this written assessment, but we are providing them now so that you can consider them generally during the overall self-assessment process.

- **Lessons Learned**
 - Barriers in implementing the practice in the department (e.g., financial, administrative, legal), both generally and specifically for the target populations with limited literacy/LEP
 - Strategies, successes, and experiences in addressing barriers to implementation
 - Factors that contributed to the success or failure of implementing the practice, both generally and for the populations with limited literacy/LEP
 - Things the department/facility would have done differently
 - Future plans to change informed consent process on the department/facility level based on self-assessment findings
 - Key items that should be included in a user's guide designed to help other providers implement this practice at their facility
 - **Perspectives on the NQF Practice**
 - Feasibility and interest in implementing the NQF practice (as specified by NQF) in your department, other departments (i.e., those specified in NQF practice 2), and the facility more broadly
 - Additional information that would be needed to implement the NQF practice at your facility
 - Differences in information needs based on facilities' past experiences with improving the informed consent process and experience with the repeat back practice
 - Whether the practice sufficiently covers all the key aspects of ensuring adequate informed consent
 - Potential changes that should be made to the NQF practice or its specifications to allow for easier implementation
-

Supporting Materials

Please attach and clearly label each of the following supporting materials:

- A. Hospital/other departments' informed consent policies. Include a copy of the hospital's overall informed consent policy and any forms and instructions for patients or providers. Also include copies of other informed consent policies from similar departments that perform invasive procedures but do not use the repeat back practice.
 - B. Department informed consent policy. Include a copy of the department's informed consent policy containing the repeat back practice and any forms and instructions for patients or providers that are unique to the specific department being evaluated.
 - C. Internal quality improvement reports. Include any relevant internal quality improvement reports or internal assessments that have been performed at the facility that may be relevant to this study – i.e., addressing informed consent or the related issues for the target limited-literacy and LEP populations at your facility.
 - D. Other. Please include any additional attachments that may be useful to NQF staff in this evaluation. Number each additional attachment and provide a brief description of its purpose/relevance to this study.
 - 1.
 - 2.
 - 3.
 - 4.
 - 5.
 - 6.
 - 7.
 - 8.
 - 9.
 - 10.
-

NATIONAL QUALITY FORUM

Appendix C

Case Study – Pilot-Adopter Hospital

During the process of identifying early-adopter hospitals, a physician at the San Francisco General Hospital (SFGH) Medical Center (affiliated with the University of California-San Francisco) inquired about implementing Safe Practice 10 as a pilot project during the timeframe of the National Quality Forum (NQF) project. Although the hospital fell outside the study inclusion criteria because it did not report already using “teach back” as a routine process, NQF staff thought that the potential value of learning from real-time implementation would enhance the case study analysis. Additionally, the institution represented a demographic—a major urban academic hospital—that was not encompassed by the three early-adopter hospitals.

Of note, nurses in the elective surgery clinic had used “teach back” for at least three years on an informal basis. The major changes that occurred in the pilot project to formally adopt “teach back” were to require physicians to use the practice and to document on a modified consent form that it had been successful. After a five-month long process of review and approval by various committees and leaders at the hospital, “teach back” was implemented at SFGH’s elective surgery clinic in August 2004.

Hospital staff completed an abbreviated version of the written self-assessment given to the early-adopter hospitals. The pilot-adopter self-assessment focused primarily on implementation issues, given the short timeframe for evaluation after the August 2004 implementation of the “teach back” practice. Additionally, NQF staff conducted phone interviews with various hospital staff involved in implementing or using the practice, including providers from the elective surgery department participating in the pilot project (i.e., chief of surgery

nurse manager, staff physician), a health educator, a risk manager, quality improvement staff, and others. The lessons learned from the real-time experiences of SFGH in successfully implementing Safe Practice 10 are described in this appendix, with their specific “teach back” practice detailed in table 1 of the project report.

The Informed Consent Process and the “Teach Back” Practice

The initial time burden of implementing “teach back” for the pilot project, which was primarily attributed to modifying the informed consent form, was considered by SFGH staff to be high—even within the limited setting of its use in one department. The meetings and steps involved in implementing the pilot project occurred over a 5-month period, and the estimated staff time spent during the process was 140 hours.

Staff members involved in implementing the practice agreed that the extensive process for doing so was simply a “necessary evil” for making changes involving the institution’s organizational structure and procedures. They noted that although having standardized educational tools to inform providers about the importance of the practice and how to use it would have been helpful, the process of review by various hospital committees and individuals still would have been necessary.

One staff member noted that although the process for initial implementation was arduous, the level of vetting and support obtained from all the individuals involved

in the process ultimately contributed to stronger buy-in by all the providers responsible for carrying out the practice. It was emphasized that if such a policy change were enacted without the opportunity for review and support of other leaders at the hospital, it would have been less likely to have been accepted and used by those surgeons in day-to-day practice. Clearly, the increased support and attention that was received from the various committees and departments during the implementation process ultimately facilitated the adoption and use of “teach back” by providers.

Policies and Procedures

- **Facility wide.** SFGH’s overall informed consent policies and forms were similar to those of other adopter and non-adopter hospitals—that is, they did not describe specific mechanisms for verifying patient understanding, such as “teach back.”
- **Elective surgery clinic.** No written policies were in place to enforce the use of “teach back” in the elective surgery clinic, for either the practice as it had been used by nurses for several years or for the pilot project-associated change. The process for ensuring that “teach back” was performed systematically was similar to that used in the adopter hospitals—for example, orientation for new employees and peer reinforcement for existing employees.
- **Documentation/forms.** Before initiation of the pilot project, physicians were required under the facility’s policy to generally document in a progress note that they had explained the procedure

to patients and explained the risks and benefits, although this did not indicate how well the patient understood such information. The primary intervention in the pilot project was the modification of SFGH's consent form for medical and surgical procedures to include a line that read, "the patient stated back, in his/her own words, the procedure or treatment that is being consented to, and associated benefits and risks." In order for the form to be considered complete, attending physicians were required to check a "yes" box next to the statement. Largely for legal reasons, staff members opted not to include a "no" option, because of the potential for liability if a document indicated a patient was unable to teach back this information.

Patient understanding of pre-operative instructions was documented by nurses on the peri-operative case preparation form, by checking a box that read, "patient/family verbalized understanding." The use of "teach back" by nurses over the past three years, however, was not documented, although staff considered future modifications to the consent form to require nurses to check a box indicating that patients were able to state the scheduled procedure in their own words.

Care for Patients with Limited English Proficiency (LEP) and Limited Literacy

Given that SFGH is a public hospital and that patients must meet certain financial criteria to receive surgical services there, the patient population is of lower socio-economic status and limited health literacy, and providers were acutely aware of this need. The hospital's location in San Francisco also resulted in a very linguistically diverse

group of patients. Thus, care for patients with LEP and limited literacy was generally the norm for all encounters.

The informed consent form was estimated by hospital staff to be written at an eighth- to ninth-grade reading level. It was available in Spanish, Chinese, Vietnamese, and Russian. SFGH offered onsite staff medical interpreters at all hours, and many of its staff members were multilingual. It also utilized a commercial phone interpreter service and had on-call interpreters for 35 languages. Budget cuts had reduced the number of onsite staff interpreters, however, and physicians interviewed commented that access and long wait times for interpreters were major problems.

Implementation Process

Similar to the early-adopter hospitals, SFGH implemented "teach back" in the elective surgery clinic because it was perceived by many staff members as the department with the most well run informed consent process and the greatest focus on patient discussion prior to surgery; the clinic also was the place where nurses already were using the practice, which would facilitate broader use by physicians. Hospital staff also reported that success in implementation there would greatly accelerate more widespread adoption throughout the facility. The project was initiated by a non-surgical physician "champion" through the hospital ethics committee and subsequently through the quality management department. This was a strategic decision viewed as important to ensure that the project would be seen as

a high-priority safety issue that would garner greater attention from surgeons and hospital leadership and give the hospital accreditation credit for work in patient safety improvement.

Comparison to Informal Use

The use of “teach back” at SFGH is not new; as noted, the nursing staff had a process for informally using it for three years. In both this use and in the pilot, the end result was similar in practice – routine use of “teach back” by all involved providers. Despite similar results, however, the process for implementing “teach back” several years ago was strikingly different and much less complex. It involved only discussion of the issues at a few nursing staff meetings, agreement by clinic nurses to use the “teach back” practice, and ongoing peer reinforcement. Because of the informality of the change and the absence of documentation of “teach back,” the committees that reviewed and approved changes associated with the pilot project were not involved in the informal change.

Changing the informed consent document in the pilot project was the primary reason for the burden of formal implementation – that is, the informal practice changes did not require review and approval by hospital committees. However, whether the strong level of surgeon buy-in for “teach back” could have been achieved through the same informal mechanisms used by the nursing staff three years ago is unclear; some staff members opined that the success of the earlier change may have been due to the culture of the department’s

nursing staff. Additionally, in the absence of formal documentation and written policies, it is unknown with what consistency “teach back” was being used by nursing staff.

Preliminary Outcomes

At the time of evaluation, there were only 14 patients (7 English speaking, 7 with LEP) during the week after the project had been initiated; thus, data about the impact of the practice at the clinic were limited (although compliance for those cases was 100 percent, as measured by physician documentation of successful “teach back” on the modified informed consent form). However, even within the one-week time-frame, one clinic nurse commented she believed that a noticeable improvement in patient understanding was evident, based on the fact that staff nurses reported spending significantly less time clarifying information for patients during the nurse’s role in the “teach back” process than before. Furthermore, all of the physicians or nurses interviewed who were involved in implementing or using the practice during the pilot project noted that “teach back” did not result in any noticeable additional time burden in discussions with patients; they also expressed strong support for the change.

One surgeon in the clinic who had been using “teach back” for many years commented that it allowed him to discover that many patients do not understand information; that it usually took only one to two minutes to complete; and that complex procedures required additional

time for discussion, but that this should be considered a necessary part of the physician's responsibility. Another surgeon said that the pilot project brought about a positive change in the informed consent process overall, resulting from the increased attention given to the importance of the discussion.

Measuring Compliance and Benefit

The format of the modified informed consent form, which included a box physicians checked to verify "teach back," was uniquely designed to permit direct measurement of compliance. Staff described plans to develop a tool to gauge reading comprehension for written patient educational materials, both in English and other languages, to supplement "teach back" as a verbal comprehension check.

A measure previously used by the hospital to gauge patient understanding was its commercial patient satisfaction survey, which included one related question: "were your questions answered in ways you can understand?" The survey question was similar to the patient understanding measures from a different commercial survey that was used by the adopter hospitals. Future research efforts would be useful to identify whether and to what extent "teach back" impacts patient understanding, particularly using metrics such as these patient surveys.

Plans for Facility-Wide Implementation

Project leaders at the hospital reported plans to evaluate the success of the change in the elective surgery clinic over a longer timeframe and to advocate for formal implementation of the practice facility wide if the change were successful, although it was acknowledged that this would require substantially more staff time. The facility-wide implementation was estimated to require an additional six months, which would mean that the total implementation time would be close to one year, including the pilot project. Staff commented that working within even this timeframe, however, would be a highly accelerated pace of change for the organization, and broader adoption had not yet occurred as of June 2005, 10 months after the initiation of the pilot project.

Implementation: Reasons for Success

Based on their preliminary experiences, all SFGH staff interviewed agreed the pilot project was a success, given the strong support demonstrated by providers in the elective surgery clinic and their commitment to use the practice. They attributed success to:

- strong support by the nurse manager, nursing staff, and chief of surgery at the elective surgery clinic, which various staff described as a "nurse-run" clinic;
- an organizational culture that emphasized improving communication with underserved populations and that continuously sought tools to facilitate communication;

- the initiative of a respected hospital physician, who was the original champion for promoting the practice; and
- the fact that the practice already was being used routinely by nurses.

Hospital staff involved in implementing the practice reported that some additional strategies were used to obtain buy-in:

- educating providers about the rates of limited literacy and LEP among the hospital's patients;
- demonstrating the evidence base for Safe Practice 10;
- highlighting the ethical issues raised by not using Safe Practice 10 in order to tap into physicians' desire to do the right thing;
- obtaining multilateral buy-in;
- focusing on the opportunity for the hospital to be an innovator and leader in the area;
- demonstrating overlap in the pilot with the patient safety priorities of the Joint Commission on Accreditation of Healthcare Organizations;
- seeking early buy-in from surgical leadership; and
- making the case that the practice actually promotes, rather than jeopardizes, effective risk management.

Although the practice was considered by all hospital staff interviewed to be a success, staff did encounter some challenges in implementing the practice—challenges that any hospital seeking to make such a change to its informed consent process could expect—including:

- **Provider training.** The task of educating, training, and obtaining buy-in from providers was a major and time-consuming component of the effort. The lack of standardized tools to educate providers and promote consistent use of the practice, and to describe how an ideal informed consent discussion should occur generally, was cited as a barrier to more rapid implementation. SFGH staff advocated for the development of standardized tools to facilitate the provider education process. (The “user’s guide” also developed through this grant is intended to provide some assistance in this regard.)
- **Provider buy-in.** Although the buy-in of SFGH physicians was achieved with relative ease, getting all physicians on-board to use “teach back” was still a challenge in some instances. Improving buy-in will require more extensive documentation of the evidence and materials targeted at convincing providers that “teach back” is an effective strategy in informed consent.

NATIONAL QUALITY FORUM

Appendix D

Case Study – Non-Adopter Healthcare Organizations and Interview Protocol

Overview

For the second major component of the project, NQF staff conducted structured interviews with various healthcare professionals and administrators at facilities that had not yet adopted Safe Practice 10. The purpose of these interviews was to obtain information about how informed consent was performed at non-adopting facilities and to identify the major barriers to implementing Safe Practice 10 at these facilities.

Interview Process

NQF staff contacted individuals from both Member and non-Member provider organizations to identify individuals knowledgeable about the informed consent process at their institutions that would participate in a telephone interview. In July 2004, NQF staff held 21 phone interviews of approximately 1 hour each with 38 participants¹ representing 18 hospitals or health systems.² Appendix A provides a list of the non-adopter interviewees.

A structured interview protocol was used (figure 1), which was developed by NQF staff with input from the Technical Advisory Panel (appendix A) and the Sutton Group. Interviewees were asked to

¹Includes some calls with multiple hospital staff present; 17 of the 21 calls were one-on-one interviews.

²Indicates the number of distinct facilities or health systems represented. In some cases, separate interviews were conducted with individuals from different facilities within the same health system; these were each counted as separate facilities.

comment on the following general issues for their facility and/or specific department:

- general characteristics of the healthcare facility, its priorities for improvement, and methods for achieving organizational change and systems improvement;
- the interviewee's role in the informed consent process;
- the current informed consent process and policies, variations in the process among departments within the facility, areas for improvement, compliance/performance monitoring strategies, and past or future changes to the policies;
- strategies to ensure adequate informed consent and communication specifically for patients with limited English proficiency (LEP) and limited literacy;
- perspectives on the feasibility of, barriers to, and needs for implementing the NQF practice at the interviewee's facility/department; and
- information that would be helpful in a user's guide designed to assist other providers in implementing Safe Practice 10.

Interviewee Characteristics

The non-adopter interviewees included physicians and nurses directly involved in providing informed consent, primarily in surgical departments, and other senior healthcare professionals involved in developing, managing, and/or implementing their hospital's informed consent policies and processes. The non-clinical departments represented included senior administration and leadership, quality improvement, interpreter services/cultural competency, ethics, patient safety, and risk management.

Hospital Characteristics

The characteristics of the hospitals and health systems that interviewees represented were, by design, diverse, including private and publicly owned hospitals (both local and Department of Veterans Affairs hospitals), not-for-profit and for-profit facilities, academic/teaching facilities, large health systems and small, standalone community facilities, and managed care provider organizations. Most facilities were large, with more than 700 beds, although the number of beds ranged from approximately 40 to 900 at individual facilities, and many facilities were part of larger health systems. The geographic location of the facilities was also diverse, encompassing 12 states across a mixture of urban and rural settings; many of the urban hospitals represented were major referral centers serving patients from outlying rural areas.

Patient Characteristics

Most of the hospitals had a substantial percentage of racially, ethnically, and linguistically diverse patients, and a few had major immigrant and refugee populations. Some hospitals reported having a majority of non-Caucasian patients, and many hospitals, both public and private, reported serving large numbers of Medicaid patients. A few hospitals reported that Hispanics/Latinos were the primary minority group, while others had a greater diversity of languages, cultures, races, and ethnicities. By and large, interviewees were unaware of the literacy levels of their patient populations. Most individuals reported they did not believe limited literacy to be a major

problem in their service area – although general figures on the high prevalence of limited health literacy in the U.S. population would suggest otherwise.³

Key Findings from Non-Adopter Interviews

There was significant concordance among the non-adopters interviewed with respect to their informed consent processes, how patient understanding was assessed and ensured, familiarity with and use of Safe Practice 10, and how implementation of Safe Practice 10 fit in with the organizations' quality and patient safety priorities.

Informed Consent Processes

Overall, with the exception of the “teach back” characteristic, the informed consent process at non-adopter facilities did not differ significantly from the process at early-adopter facilities.

General

The informed consent processes at interviewees' facilities generally were similar to one another and to those at early-adopter facilities. Physicians were responsible for discussing information about medical treatments and procedures with patients, and patients were asked to sign an informed consent form to indicate that this discussion had occurred and to agree to the recommended procedure. However, the individual who was responsible for discussing information with patients and obtaining signatures varied among facilities. Although it was

primarily the duty of physicians, sometimes the discussion or signature task was delegated to nurses, physician assistants, or medical students. Additionally, nurses often were required to witness patient signatures; in these cases, nurses also signed the informed consent form. Nurses also were responsible for checking patient charts at multiple points in the presurgical care process to ensure that the informed consent forms were properly completed and to offer patients additional information and give them the opportunity to ask questions before procedures.

Formal Hospital Policies and Forms

Consistent with the adopter hospitals, many interviewee facilities' informed consent policies were designed primarily to be in compliance with legislative regulations and professional standards of care. These policies generally addressed the importance of communication, but did not include specific requirements about ascertaining patient understanding.

Many interviewees reported that changes to facility or department informed consent policies occurred on a frequent, sometimes annual, basis. These changes were largely in response to legislative changes (e.g., use of interpreters for compliance with federal Department of Health and Human Services Office for Civil Rights regulations) or quality improvement needs (e.g., detail about what risks and benefits must be disclosed during discussions). Implementation of “teach back” could be greatly facilitated if it occurred as part of

³Institute of Medicine, *Health Literacy: A Prescription to End Confusion*, Washington, DC: National Academies Press; 2004.

other such modifications to facilities' broader informed consent processes, although interviewees did not strongly indicate that other routine informed consent process changes were well known or widely advertised within their organizations.

The structure and design of informed consent forms varied widely. Some facilities used a single, generic form for all procedures and treatments requiring informed consent, while others had separate forms (e.g., for medical treatments, surgical procedures, blood transfusions, and anesthesia). Individual departments were responsible for developing or tailoring their own informed consent forms in some instances, and these forms might detail the risks and benefits of specific procedures or interventions commonly performed in the department.

In addition to patient signatures on consent forms, documentation about informed consent discussions sometimes, although rarely, occurred in patient medical records. Some providers reported using narrative documentation to indicate that an informed consent discussion had occurred and/or to document more specific information about what risks and benefits were disclosed during the discussion. This narrative documentation was required in some facilities, and it was encouraged, but not monitored or enforced, in others.

Performance Monitoring

Many mechanisms were used to monitor compliance with hospital policies around informed consent, and compliance with those policies generally was defined by proper completion of consent forms

(e.g., patient signatures), without required documentation about the discussion or demonstration of patient understanding. At all facilities, nurses were responsible for routinely checking patient charts during the care process to ensure that consent forms were signed before treatments and procedures began. Additionally, interviewees reported that the following strategies were used to monitor performance related to informed consent: periodic chart audits; sporadic floor audits of patient charts; and quality and case reviews when specific issues arose. At some facilities, there were no audits beyond routine checking by nurses during the care process.

Quality of Existing Informed Consent Process

Although some providers interviewed expressed confidence that their consent processes were adequate and felt that patients were usually well informed, a number of interviewees – both provider and non-provider – raised concerns about the consent processes at their facilities, including the following:

- **Patient factors.** The ability to comprehend information and make informed decisions was affected by emotional stress (particularly for those faced with decisions immediately after learning about serious diagnoses), cultural issues, educational/literacy levels, and language barriers.
- **Quality of discussions.** Factors affecting the quality of informed consent discussions included too much physician focus on completing the consent form; the qualifications of the individual giving patients information; limited staff time to engage in discussions and clarify

information; and inconsistency in what information individual providers disclosed to patients. Several interviewees noted that there were no or insufficient mechanisms to monitor how well physicians performed informed consent with respect to a full dialogue and patient understanding.

- **Provider attitudes.** The quality of informed consent discussions often varied based on the individual physician's attitudes toward the importance of the discussion. Concerns were raised about lack of staff education and commitment to informed consent and patient understanding by some providers, and avoidance of active communication strategies such as "teach back" in favor of passive ones, such as asking "do you understand?" to facilitate the process.
- **Forms.** Many interviewees reported that their facilities' informed consent forms were difficult to read because of the volume of information, complex legal and medical terminology, small print, lack of translated forms, and high reading levels. Others, however, commented that their forms were too generic and overly simplistic, without useful information about the actual risks, benefits, and alternatives for specific surgical procedures.

Ensuring Patient Understanding

When asked how providers ensured that patients understood information related to their care, interviewees generally responded by describing passive techniques (e.g., providing written information without active patient involvement to gauge comprehension), or, in several instances, by acknowledging that there simply were no mechanisms in place that providers

routinely used to ensure patient understanding.

Limited Literacy

As noted, interviewees were largely unaware of the extent of limited literacy in their patient populations. With the exception of public hospitals serving primarily patients of low socioeconomic status, most interviewees—physicians and nurses alike—expressed the belief that lack of understanding was not a problem in their English-speaking patients. A few providers acknowledged that they did not know whether patients understood the verbal or written information they received and that their facilities lacked resources to address the issue. Training on how to detect limited literacy was generally minimal or non-existent and was based on providers' subjective judgment. Several providers asserted that asking patients "do you understand?" and "do you have any questions?" was sufficient to ensure full comprehension.

The informed consent forms and educational materials at interviewees' facilities were of variable levels of difficulty. Several interviewees judged them to be between the sixth- and eighth-grade reading levels, although most were uncertain and could not confirm whether the forms had been formally tested for readability. Some providers commented that the reading level of the forms, and the extent of the information on them, was unimportant and irrelevant to patient understanding, because all of the important information was provided during verbal discussions. Individuals reported various other tools

that were available to assist with the education of patients with limited literacy or difficulty understanding, including videotapes, pictograms, and physical models of body parts.

Patients with LEP

The non-adopter facilities had the usual array of interpreter services for patients with LEP to assist in informed consent discussions, including onsite interpreters for languages common among the facilities' patients, on-call interpreters, multilingual medical staff, and commercial telephone interpretation services. Interviewees raised issues involving the use of interpreters that were similar to those raised by adopter hospitals—access and availability, wait times, and quality of interpretation. The informed consent forms were available in Spanish and English at many facilities; in English only at some facilities; and in many different languages at a few facilities.

Current Use of Safe Practice 10

Because the individuals interviewed were at facilities that were not early adopters of the NQF-endorsed Safe Practice 10, NQF staff sent the written practice and its specifications to each interviewee in advance of the phone calls and described Safe Practice 10 during each interview.

“Teach Back”

Many interviewees were already familiar with the “teach back” practice in general, although a number of individuals had never heard of asking patients to recount information as a way of verifying understanding. A few interviewees reported use

of “teach back” by some physicians, nurses, and interpreters at their facilities, although it was not used routinely for all patients. Few knew specifically about Safe Practice 10.

Although NQF staff explicitly solicited interviews from individuals at facilities that had not been using the “teach back” practice routinely or systematically, which would make the facility an adopter hospital, several interviewees reported that the practice was indeed in use in this manner at their facility. “Teach back” was largely used for procedure, site, and side confirmation prior to surgery in these instances, but sometimes also to demonstrate greater understanding about the risks and benefits of surgery. Only one interviewee reported that “teach back” was specified in a written policy, as part of the policies and procedures for interpreted encounters. Without more detailed assessments, however, it was not possible to gauge how systematically “teach back” actually was used at those facilities.

Additional Specification 1: Simple Sentences and Multilingual Forms

A mix of responses was received regarding whether informed consent forms used simple sentences and/or were available in the patient's primary language. Informed consent forms' reading levels were variable, as noted earlier, and a number of interviewees perceived them to be too complex. Not all hospitals had forms available in the primary language of non-English-speaking patients, and this issue was particularly true for the less commonly spoken languages.

**Additional Specification 2:
Engaging Patients in a Dialogue**

Most interviewees agreed that patients were engaged in a dialogue about information included on the consent form, although some acknowledged that the quality of this dialogue may not be adequate.

**Additional Specification 3:
Providing Interpreters and Readers**

All hospitals had some interpreter services available to assist patients with LEP and visually or hearing-impaired patients in the informed consent process. Some interviewees stated they would read informed consent forms to those unable to read. Most acknowledged that there were no specific mechanisms in place to assist patients with limited literacy, other than patients who were known to be fully illiterate; nurses assisted these individuals with tasks that required reading or writing.

**Additional Specification 4:
Volume-Outcome Disclosure for High-Risk Surgery**

No facilities reported using this practice, and nearly all interviewees strongly opposed it or were confused about what it entailed. Concerns raised about this practice were possible liability for disclosing information that patients may be at higher risk with a low-volume provider; perceived senior leadership disapproval of disclosing such information due to the potential liability risk; increasing patient fears about risk and provider competence; lack of clarity regarding whether the specification referred to individual surgeons or the facility overall; mixed evidence on the volume-outcome link; and unwillingness by surgeons to disclose this information.

**General Priorities and Processes
for Organizational Change**

Implementation of Safe Practice 10 could be facilitated by linking it to existing priorities for improvement at healthcare facilities. An understanding of the processes that must occur within those facilities in order to generate change also is needed to ensure successful adoption of the practice.

Hospital Priorities

Interviewees were asked to identify the major issues facing their facilities currently, in order for NQF to gain perspective on how informed consent process changes might fit relative to other priorities for quality improvement. The major areas included decreasing Medicaid reimbursement; malpractice issues; use of information technology and transition to electronic medical records; capacity issues with increasing patient demand and fixed resources for providing care; patient safety and medication errors; market share and competition; staff turnover in teaching hospitals; and nursing staff shortages. With the exception of the few individuals who responded that patient safety and meeting the needs of culturally diverse/patients with LEP were high priorities for improvement, informed consent and implementation of practices such as Safe Practice 10 were not among hospitals' top priorities.

Quality Improvement Efforts

Interviewees provided examples of successful efforts to change existing processes that addressed efficiency, delays in care, patient satisfaction, and patient safety. They attributed the success of these changes to having leadership support, the financial capacity

and staff resources to initiate the changes, and buy-in on the part of all involved participants that an important problem existed and that the proposed solution would be effective in remediating it. These same factors were present in the adopter hospitals' experiences and were attributed to their success in implementing the "teach back" practice.

Requirements for Organizational Change

The various quality improvement initiatives described by interviewees often required the initiative and coordination of a single champion of the change, which had been a physician, nurse, or other senior staff member, and also the convening of at least one performance improvement team to develop the plan for enacting the change. Organizational change often required multiple levels of review and approval by various hospital committees and leaders, which was similar to the experience of San Francisco General Hospital (SFGH), the "pilot-adopter" hospital (appendix C). The perceived needs for implementing the "teach back" practice by non-adopter interviewees also showed many similarities to the steps taken by SFGH, including the following:

- **Provider education.** By and large, provider education was the most commonly cited need for successful implementation, and the task of educating all providers within a facility – particularly large and teaching hospitals with constant turnover of medical residents – was considered to be a major barrier. Interviewees suggested several mechanisms for educating providers across a large facility, including department meetings, e-mails, leadership reinforcement, and incorporation into

standardized, intranet-based training modules for all medical staff.

- **Committee and leadership review and approval.** The involvement of numerous departments and committees also was cited as necessary for implementing change in the informed consent practices at non-adopter facilities, including risk management/legal, ethics, forms, medical and nursing leadership, facility leadership, and quality improvement. Most interviewees also noted that their facilities would need to convene a project team specifically to study the issue, review the evidence behind the change, develop a plan to implement the change, and coordinate the processes needed to achieve it. One physician commented that "things at hospitals just take time," and that simply mandating a practice without these levels of review and approval would result in failed implementation.
- **Departmental versus facility-wide differences.** Interviewees drew a distinction between the need for implementation on a department level versus broader, facility-wide change, noting that the burden of implementation and provider education were substantially less at the department level.

Making Informed Consent a Priority

There were comments on how to make improving informed consent a priority for change – particularly with respect to implementing "teach back" and the other specifications of Safe Practice 10. Interviewees identified the following factors that could impact their facilities' desire to implement the practice:

- **The NQF “brand.”** The impact of NQF endorsement on interviewees’ interest in implementing the practice was variable. A number of individuals reported that NQF’s credibility and the level of review already performed were positive factors, and that leaders would respond strongly to a change that was endorsed by NQF. Several physicians, however, responded that the endorsement had little to no impact because they were not familiar with NQF. Others noted that the NQF endorsement was “icing on the cake,” but that ultimately the change would be made because “it’s the right thing to do.”
- **Evidence and demonstrated value of the practice.** Physicians must be convinced that there is a major problem with their communication techniques and informed consent processes and that that the practice would be effective in addressing it. Many individuals asked for data and scientific evidence to demonstrate the value and effectiveness of Safe Practice 10, noting that physicians were more likely to respond to changes that were backed by scientific evidence.

Most individuals perceived that the major difference that Safe Practice 10 would make would be to increase time for the patient encounter, which would be considered a major burden and a barrier to using “teach back.” Several physicians did not think their informed consent processes were problematic and did not believe that practices such as “teach back” were needed to improve patient understanding. On the other hand, others added that using the practice would allow them to know how well patients understood information, where currently no mechanism was available to make this assessment. Given the varying responses of non-adopters to

the usefulness of the practice, the need to improve provider buy-in was abundantly clear.

- **Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or regulatory mandates.** Some individuals commented that only a requirement by JCAHO or a legislative/regulatory mandate to perform the practice would be effective in getting providers to use it; until then, voluntary use would occur only in an ad hoc fashion. Others, however, noted that simply making Safe Practice 10 a requirement and incorporating it into a formal policy would not ensure that it was actually performed and that provider buy-in would still be needed for it to be used.
- **Leadership support/mandates.** Less restrictive than a regulatory mandate, leadership support of the practice and/or requirement for all providers to use it was cited as a necessary and powerful tool for change within hospitals and healthcare systems. Involving leadership and staff at multiple levels within an organization in supporting and implementing the practice was identified as being critical for successful implementation of Safe Practice 10.

Facilitating Global Adoption

Beyond individuals’ own facilities, broader adoption of the NQF practice by U.S. healthcare providers will require the conditions described above as well as others, including the following:

- **Professional publicity.** Featuring information about Safe Practice 10, in particular its evidence base, at professional conferences and in medical publications, and promoting it in medical education curricula, would

familiarize providers with it and could ultimately encourage them to use it.

- **Link to broader quality and patient safety issues.** Current interest in quality and safety by national groups such as the Centers for Medicare and Medicaid Services, JCAHO, and the Leapfrog Group is high, which influences providers' desire to make improvements in these areas. Tying informed consent process improvements using Safe Practice 10 to these broader issues, as was done by the pilot adopter hospital, would promote the spread of the practice.
- **Professional association support.** Gaining the support of groups such as the American Medical Association and the American College of Surgeons would lend credibility to the practice and promote provider buy-in, because physicians in particular remain very skeptical about the benefits of the practice.
- **Patient education.** Educating patients on how to take control of their medical care and to be proactive in being involved in decisions about treatments and procedures, for ethical as well as patient safety reasons, would create a demand for improved communication by providers.

Information Needs: User's Guide Input by Non-Adopters

The feedback received from non-adopters was central to the development of *Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals*. In addition, many non-adopters also cited the need for standardized training modules for providers (e.g., on informed consent issues, communicating with patients with limited literacy, using interpreters for patients with LEP) and for patient education resources such as videotapes and model consent forms that could illustrate how language should be simplified. Although the development of these additional resources was beyond the scope of the NQF project, clearly, additional work is needed to ensure that patients are well informed.

FIGURE 1. INTERVIEW PROTOCOL FOR NON-ADOPTER HEALTHCARE ORGANIZATIONS

I. GENERAL BACKGROUND

Interviewee Information

Name, degrees: _____

Title, department: _____

Organization: _____

Interview date: _____

Interviewer: _____

- What is your general role at the hospital, and how are you involved in the informed consent process at your facility/department?
- What is your interest in the NQF project and our practice for informed consent, and what do you hope to learn from participating in this interview?

Hospital Characteristics. Briefly describe your hospital, including the:

- Geographic service area and patient demographics (e.g., race/ethnicity, languages spoken, and literacy levels)
- Bed size
- Major services provided
- Ownership, etc. (e.g., not-for-profit/for-profit, public/private, academic/community)

General Hospital Priorities

- What are a few of the biggest issues facing your facility today?
- Can you describe an example from your experiences at the hospital where a new process or procedure was put in place in an effort to improve quality, particularly in patient-centered care (e.g., patient communication, education)?
 - How did that kind of change become a priority at your organization? Who was responsible for initiating that change, and what was required to accomplish that change?
 - Was it successful? If so, what contributed to the success? If not, what do you think led to the lack of positive results?

II. FACILITY/DEPARTMENT'S CURRENT INFORMED CONSENT PROCESS/POLICY

- Describe the informed consent process for your facility/department as it actually occurs on a daily basis, including the individuals involved and the tasks each is responsible for performing in the process.
 - What formal policies and documents are in place to guide this process?
 - Do they differ between departments?
 - Are there different consent forms (e.g., medical vs. surgical)?
- How does your facility/department ensure the informed consent process is being followed according to the policy – is performance monitoring done?
- Has your facility/department taken any steps to improve the informed consent process or forms? What were they, and were they effective?
- How does your facility/department know the extent to which patients truly understand the information they receive about their healthcare, particularly about the risks, benefits, and alternatives of the procedures and services they receive? Are there specific mechanisms or processes in place to follow-up and ensure patients understand, particularly with limited literacy and patients with LEP?
 - Are there any tools available to assist with ensuring informed consent (e.g., translated forms and information, drawings)?

continued

continued

II. FACILITY/DEPARTMENT'S CURRENT INFORMED CONSENT PROCESS/POLICY

- Are there special provisions in place to address the needs of limited English proficiency patients? Are the informed consent forms available in foreign languages, and which ones?
- Are there any special tools/provisions to address the needs of patients with limited literacy? Have your informed consent forms been assessed for readability, and at what grade reading level are they?
- What concerns do you have about the informed consent process as it currently occurs at your facility/department, and how might those issues be resolved?
- Do you have any specific examples of challenges your facility/department has encountered with informed consent? Can you name a few specific areas of the process of obtaining informed consent that are especially problematic?

III. SAFE PRACTICE 10/NQF'S INFORMED CONSENT PRACTICE

Please see the specifications for the NQF practice, which can be found in the document attached to the e-mail you received confirming this interview time.

- How familiar are you with a practice like the NQF-endorsed one for informed consent (both the "repeat back" aspect and other specifications)?
 - Are any components of the NQF practice currently in use at your facility/department (e.g., multi-language informed consent forms)?
 - What difference would it make within your facility/department if the NQF practice were implemented, compared to any steps you've taken to improve informed consent in the past?
- Imagine you were asked to implement this practice at your facility/department.
 - What would you have to do— who would need to approve such changes?
 - Discuss your thoughts about the ease, feasibility, and burden of implementing the NQF practice at your facility/department.
 - What would the barriers be to implementing this successfully?
 - Would different providers within the facility/department view implementing the practice as more or less burdensome? What could be done to improve provider buy-in and willingness to carry out this practice?
 - Is the practice specific and clear enough for you to implement?
 - What other questions, concerns, or doubts would you or others in the facility/department have, about how to carry it out based on how it is specified by NQF?
 - Are there any other changes that could be made to the practice that would improve its ability to address the needs of your facility/department or that would make it easier to implement?
- Do you have any plans or desire to implement the NQF practice or make other changes to your informed consent process in the near future? If so, what specific changes are planned, and what prompted the desire for these changes?
- What factors would make you more willing to adopt the NQF practice at your facility/department? What could be done or what would be needed to motivate or encourage your facility/department to adopt the practice?
 - How much does the fact that this practice has been endorsed by NQF, a national forum of consumers, providers, healthcare professionals and others, as a voluntary consensus standard for patient safety affect your facility/department's interest in adopting this practice?
- What specific types of information would you like to see included in a user's guide designed to assist you in implementing this practice? What kinds of tools would be useful to include in a user's guide for providers (e.g., more detailed guidelines, improved tools, documented results, etc.)?
- On a more global basis, what do you believe could be done to facilitate adoption of the NQF practice more broadly by other providers?

NATIONAL QUALITY FORUM

Appendix E

Workshop Proceedings

Overview

The National Quality Forum (NQF) held an invitational workshop on September 10, 2004, in Baltimore, Maryland, that brought together various project participants and other relevant stakeholders. At the workshop, NQF staff provided an overview of the preliminary project findings and case study; representatives from early-adopter hospitals and the pilot-adopter hospital described their facilities' experiences using "teach back" (a term that was recommended by members of the Technical Advisory Panel, staff at early-adopter hospitals, and experts in limited literacy to replace "repeat back," because of a stronger link to comprehension); and workshop participants discussed the major issues associated with using and facilitating broader adoption of Safe Practice 10 by U.S. healthcare providers. Workshop participants included stakeholders with expertise in patient safety, cultural competency, language services, limited health literacy, informed consent, surgery, risk management, and ethics. The workshop was open to NQF Members and was chaired by Gregg A. Pane, MD, MPP, Director of the District of Columbia Department of Health. Appendix A includes a list of the workshop participants. A summary of the workshop discussion follows.

Perspectives of Adopter Hospitals

The following representatives from the adopter hospitals presented on their experiences with using “teach back,” providing commentary on the barriers and challenges faced, lessons learned, and recommendations for other institutions interested in adopting the practice:

- Claudette Dalton, MD, Assistant Professor of Medical Education and Anesthesiology, University of Virginia Health System (UVA)
 - Sylvia Ines de Trinidad, MPH, Health Educator, Patient Education, San Francisco General Hospital (SFGH) Medical Center
 - Irwin Koransky, MS, CPHQ, Director of Quality Management, Shriners Hospitals for Children-Los Angeles
 - Silvia Schrage, MA, ABD, Manager, Cross Cultural Communications, Sherman Hospital, Elgin, IL
- **“Teach back” can be sustained in the long term.** Although there was an initial learning curve for providers to use “teach back,” the ease of use of the practice increased over time. Furthermore, routine use of the practice by providers was sustainable in the long term, given adequate leadership support and buy-in by all relevant providers to encourage using “teach back” as a routine part of the care process.
 - **Improving patient involvement in care.** “Teach back” practice increases patient involvement in the decisionmaking process, engaging patients in their own care.
 - **Increased adherence with instructions and fewer missed appointments.** After the implementation of “teach back” at UVA, the cancellation/delay rate for surgeries fell from 8 percent to 0.8 percent. The high cancellation/delay rate was traced to poor patient comprehension of instructions, many resulting from misunderstandings that could have been clarified during the pre-operative process and informed consent discussion.

Benefits

There was general agreement that the benefits were high and the burden was low when using “teach back.” The major positive outcomes named by individuals from early adopters of Safe Practice 10 included the following:

- **Valuable improvements in patient safety and quality.** “Teach back” provided an opportunity for patients to clarify and confirm their understanding of procedures, thereby improving the provider-patient communication process and potentially preventing medical errors.

Barriers

Common barriers in the informed consent processes at adopter hospitals, which workshop participants generally agreed also were likely to occur in most hospitals, included the following:

- **Informed consent forms written at high reading levels.** Because these forms were generally centered around legal protection of hospitals and physicians, they were not designed to provide sufficient information to support patient decisionmaking. Making changes to these forms was identified as difficult because of the various hospital

committees that must review modifications and the challenges involved in simplifying language on the form while retaining the necessary legal information.

- **Lack of awareness and services for patients with limited literacy.** Often, there were no formal or effective approaches to meet the needs of patients with limited literacy. Providers often were unaware of the extent of limited literacy, with the issue being a “hidden problem,” and English-speaking patients with limited health literacy were frequently overlooked.
- **Subjectivity in interpreting the adequacy of “teach back.”** Even for providers who had been using “teach back” for a long time, some subjectivity in judgment was needed to determine whether patients’ “teach back” responses indicated adequate understanding. Workshop participants raised questions about whether and how minimum thresholds could be established to define what constituted adequate patient understanding in the “teach back” process.
- **Provider resistance to using “teach back.”** Any hospital is likely to have some providers who are resistant to using “teach back,” particularly physicians who are frustrated with the perceived time burden required to use the practice. Getting buy-in from these physicians was a critical barrier to successful implementation.
- **Challenges in providing adequate language interpretation.** For all encounters requiring language interpretation, including those related to informed consent discussions, providers faced numerous challenges: limited availability of interpreters, particularly for languages other than Spanish; difficulty in properly

translating medical terminology/concepts and a lack of well-established resources for meeting this need; and lack of reimbursement by federal and state agencies or third-party payers for the high cost of interpretive services.

- **Lack of patient involvement in care.** Patients frequently relied on physicians to make decisions and were reluctant to ask questions. Patients often would ask nurses to answer questions after physicians had left the room (questions that the nurses could not answer). Limited health literacy and patients’ general passivity in communicating with physicians about their care were commonly cited as factors that decreased the quality of discussions related to informed consent and medical decisionmaking.

Unique Issues by Hospital

Individuals from adopter hospitals highlighted a number of unique issues encountered that resulted from the particular aspects of the organization, provider culture, or patient population at their facilities – although many of these issues are likely to be characteristic of other hospitals as well.

SFGH Medical Center

As a public, safety net hospital whose primary population is patients with limited literacy, low socioeconomic status, limited English proficiency (LEP), and a large number of diverse cultural and linguistic backgrounds, SFGH’s providers were particularly attuned to the need for adequate communication. Surgeons using “teach back” had an underlying expectation that patients did not understand. Because

SFGH is a teaching-affiliated hospital with a constantly rotating staff of medical residents, nurses in the department implementing “teach back” also were particularly aware of the need for constant education and reinforcement of the use of “teach back” by resident physicians. A brief but effective education program that addressed the hectic schedules of rotating staff was critical to the continued use of the practice. Finally, providers at SFGH sometimes questioned the accuracy of interpreted encounters, potentially raising additional challenges in the use of “teach back” for patients with LEP.

Sherman Hospital

A standalone community hospital with a strong commitment to providing adequate interpretive services, Sherman Hospital utilized innovative strategies to ensure patients with LEP received quality care. Many written materials were not made available to providers in Spanish, in order to encourage providers to call interpreters when they were needed. Additionally, interpreters were empowered to be patient advocates and intervene when it appeared providers were not communicating effectively with patients with LEP—although this potentially raised the issue of whether interpreters were overstepping their professional boundaries. The provider culture at Sherman also was strongly physician driven, and there was strong resistance to physician use of “teach back,” with the practice almost solely being used by nurses. However, nurses used unresolved patient questions as a red flag to indicate that informed consent had not

been obtained, and they called surgeons to answer patient questions before surgery was initiated if needed. Finally, hospital staff from various departments reported that the informed consent process varied among departments and that the primary department performing “teach back” was regarded as being the most thorough in informed consent.

Shriners Hospitals for Children-Los Angeles

Given the low socioeconomic status of its patient population, Shriners Hospitals’ patients often did not ask questions, in order to avoid appearing unintelligent or uninformed. Many patients were of foreign nationalities and deferred to physician autonomy in decisionmaking, which was attributed largely to a more submissive cultural attitude toward physicians. Because patients generally were referred to the hospital because of their interest in receiving elective surgery, refusal of care was not a major issue. Patients often were not interested in the details of surgeries, including the risks, particularly because the limited procedures performed at the hospital—orthopedic and burn reconstruction—generally had minimal risks and were not related to life-threatening conditions. The aspect of informed consent that presented the greatest issue involved patients having expectations that exceeded realistically achievable outcomes.

UVA

As a large academic teaching hospital known to have a large proportion of patients with limited literacy, some departments at UVA were particularly attuned

to the issue of limited literacy, although awareness of the issue required constant provider education. Furthermore, most physicians were uninformed about how to properly work with interpreters, and no quality improvement monitoring was in place regarding the adequacy of interpreter translation. Finally, the organization's bureaucracy required four committees to change language on its informed consent document, and the form contained excessive legalese.

Recommendations

Based on their experiences and lessons learned, both in the past and during the project's assessment process, representatives from adopter hospitals provided a number of recommendations for 1) how NQF could facilitate broader adoption of Safe Practice 10 by other providers and 2) how providers could successfully implement Safe Practice 10. Workshop participants shared their experiences and provided additional recommendations.

Recommendations for NQF

- make the case for “teach back” to become a necessary and routine part of the care process, establish its link to safety and quality, and emphasize the relatively low burden/cost of long-term use;
- provide convincing data to physicians about the benefits of using “teach back”;
- educate providers, including residents and medical students, on the importance of adequate informed consent and the effectiveness of “teach back”;
- establish outcome measures and/or evaluation instruments that are linked to the informed consent process; and
- work with regulatory and accreditation bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to incorporate “teach back” into their standards.

Recommendations for Healthcare Facilities

- clarify interpreter, physician, and nurse roles in “teach back” and the informed consent process generally;
- promote standardization of the informed consent process throughout facilities;
- improve documentation of the informed consent discussion in patients' records;
- develop metrics to help providers determine whether patients with LEP can complete the informed consent process without an interpreter;
- ensure proper training and reinforcement on the use of “teach back” for all individuals involved in the informed consent process – physicians, nurses, interpreters, and other relevant healthcare providers – and develop a standardized training program to assist with this;
- apply “teach back” in other departments, both for informed consent and in other appropriate situations, and establish institution-wide, written policies to implement “teach back” that include consideration of special circumstances for patients with LEP (e.g., language competency standards for bilingual providers);
- eliminate process gaps between the time physicians explain surgical procedures and the time patients sign informed consent forms whenever possible;

- provide health education information related to informed consent to patients (e.g., mentioning “teach back” in patient safety brochures);
- modify informed consent forms so that English and other languages are side-by-side on the same form, to include interpreter attestation, and to document the type of interpretation provided;
- simplify informed consent forms to lower reading levels;
- have interpreters utilize a “who, what, where, why, and ‘whoa’” approach as a way of ensuring subjective and adequate interpretation and comprehension, which calls for patients to demonstrate understanding of each of these five elements (“whoa” represents a chance for patients to stop and ask questions);
- identify champions within healthcare facilities to implement informed consent process improvements such as “teach back,” and obtain management/leadership support; and
- ensure sustained efforts with adequate resources, especially for ongoing education and monitoring, are in place to support changes to the informed consent process, because “quick fixes” will fade.

Recommendations for Healthcare Providers

- be careful when explaining the benefits and emphasizing the limitations of elective surgical procedures. Patients’ expectations often exceed actual outcomes, sometimes creating disappointments;
- communicate with the assumption that no patient understands the information presented, rather than with the assumption that a lack of questions means the patient understands. Be aware that many patients may have questions,

but will not ask them because they are afraid of appearing unintelligent or uninformed. Patient respect is key, and it is important to remember that patients with limited literacy do not like to be singled out or explicitly identified as such; and

- allow adequate time for patients to express themselves, and leave sufficient time for patient education and discussion.

General Discussion Issues

Workshop participants generally agreed with the recommendations made by individuals from adopter facilities and provided additional perspectives based on their diverse interests. They additionally considered findings from the non-adopter interviews, as described in appendix D, discussing the major challenges identified by providers who have not implemented “teach back.” A few key issues emerged during the workshop discussion as the major leverage points for how to improve informed consent, how to promote the use of Safe Practice 10 by other providers, and how to improve care for patients with LEP and limited literacy.

Informed Consent

Workshop participants agreed that consent forms are in urgent need of revision, particularly with regard to reading comprehension levels, in order to ensure that patients can understand the information on them. Questions were raised about the most effective way of standardizing the content on informed consent forms, with

additional issues arising when translation into different languages was needed.

Participants noted that verbal communication by providers also needed to be improved and that both the medical education systems and practice settings should focus on enhancing provider communication skills.

Additionally, participants emphasized that patients should be involved in and educated about the informed consent process to a much greater degree. It was also noted that a thorough informed consent process requires time for patient discussion and consideration well in advance of surgical procedures, whenever possible, although this should be balanced with the need to hold discussions close enough to the day of a procedure (e.g., within 30 days) to ensure that the patient still remembers information from the discussion when the procedure is performed (recall of this information has been shown to decrease over time).

Finally, workshop participants noted that nurses are often left to fill in gaps when patients do not fully understand information related to their care. This is undesirable in part because nurses are not always qualified to answer all of the questions posed by patients and/or because hospital policy or state law usually names physicians as the responsible party.

Safe Practice 10

Workshop participants concluded that having a champion or advocate, and management support, would greatly ease the implementation burden of “teach back.” Ongoing training and reinforcement of all

involved hospital staff also was considered to be critical to ensuring routine use of the practice, but providers needed to be convinced of its benefits as well.

It also was noted that hospital administrators should be targeted and presented with a stronger business case for using the practice, because many providers and administrators do not consider informed consent to be an important issue. Participants also noted that, on a broader, policy level, both incentive-based “carrot” (e.g., tort reform) and regulatory “stick” approaches (e.g., JCAHO) could be used to promote the use of Safe Practice 10.

Patients with LEP and Limited Literacy

Workshop participants noted that many of the common methods of gauging quality improvement were not meaningful for patients with limited literacy—for example, patient satisfaction surveys that were written at high reading levels. For patients with LEP, there were numerous issues regarding the availability and competency of interpreters.

Workshop participants also questioned interpreters’ roles in promoting better informed consent, because allowing interpreters to intervene as patient advocates may cross professional lines for subjective interpretation. Viewing interpreters as advocates for communication—and not as representing the patient or provider—was suggested as one possible strategy for improving interpreter involvement.

Finally, some workshop participants questioned the degree to which interpreters should be held accountable for patient understanding during informed

consent, with some individuals raising concern about whether interpreters should be required to sign consent forms, as they do in some hospitals.

Workshop Conclusions and Recommendations for Action

Workshop participants agreed that much work is needed to address the needs of all patients in order to ensure quality care during the informed consent process, particularly for those with LEP or limited literacy. Many also commented that the “teach back” practice is a promising method and that a number of strategies were identified throughout the workshop regarding ways in which to promote the broader use of Safe Practice 10. The workshop concluded with participants describing take-home messages learned from adopters and actionable recommendations for both providers and NQF:

- **Standardizing interpreter interactions with patients.** Providing standardized scripts for interpreters’ informed consent conversations with patients would ensure consistency in the information received by patients with LEP. Greater standardization in interpreter practice, in general, also would greatly benefit patients with LEP – that is, by the promulgation of a code of ethics and professional conduct for interpreters.
- **Modifying consent forms.** The informed consent form was named as one major leverage point for process improvement, and participants commented that modifications could be made to the form that would promote the use of “teach back” – that is, by adding a section that requires documentation that “teach back” had been used successfully. Informed consent forms also should document how interpretation was performed, if applicable (e.g., by a trained interpreter, the provider, or a commercial phone service).
- **Focus on patient-centeredness.** Patient participation was highlighted as a key element of the informed consent discussion, and patient respect and participation in decisionmaking were essential to improving outcomes and establishing a strong physician-patient partnership in the treatment process. The entire informed consent process can and should be simplified, with a revised model centered on patients’ needs.
- **Targeting the provider community.** Many hospitals and providers are simply unaware that inadequate patient comprehension, lack of informed consent, and limited literacy are so common. Increasing hospital and provider awareness of these issues would result in greater provider interest in using Safe Practice 10 and also would help gain the leadership support and champions needed for broader use of the practice.

NATIONAL QUALITY FORUM PUBLICATION INFORMATION

Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy – An Implementation Report

Document No.	Description	Member Price*#	Non-member Price#
NQFIR-01-05	Paperback, 104 pages	\$20.50 each, incl. shipping & handling (additional 10% discount on bulk orders of 10 or more copies shipped to one address)	\$27.50 each, incl. shipping & handling (10% discount on bulk orders of 10 or more copies shipped to one address)

Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals and A Provider's Guide to Informed Consent are free online at www.qualityforum.org.

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