HHS Public Access

Author manuscript

Jt Comm J Qual Patient Saf. Author manuscript; available in PMC 2018 June 28.

Published in final edited form as:

Jt Comm J Qual Patient Saf. 2018 June ; 44(6): 343–352. doi:10.1016/j.jcjq.2017.11.010.

Opportunities to Improve Informed Consent with AHRQ Training Modules

Sarah J. Shoemaker, PhD, PharmD,
Senior Associate and Health Services Researcher, Abt Associates, Cambridge Massachusetts

Cindy Brach, MPP,
Senior Health Care Researcher, Agency for Healthcare Research and Quality, Rockville, Maryland

Alrick Edwards, MPH,
Senior Analyst, Abt Associates, Durhan, North Carolina

Salome O. Chitavi, PhD,
Project Director, Division of Healthcare Quality Evaluation, The Joint Commission, Oakbrook Terrace, Illinois

Rene Thomas, RN, BSN, and
Associate Project Director, Division of Healthcare Quality Evaluation, The Joint Commission

Melanie Wasserman, PhD
Managing Consultant, The Lewin Group, Falls Church, Virginia

Abstract

Background—Informed consent is a process of communication between clinician and patient that results in the patient's decision about whether to undergo a specific intervention. However, patients often do not understand the risks, benefits, and alternatives, even after signing a consent form.

Methods—Mixed-methods pilot test of two Agency for Healthcare Research and Quality (AHRQ) informed consent training modules implemented in four hospitals. Methods included staff and patient surveys, interviews, site visits, and pre- and posttests of the modules.

Results—A low proportion of clinicians reported using teach-back (40.0%) or high-quality decision aids (55.0%). Patients reported limited use of best practices, including being asked to teach-back (58.4%), having other options described (54.9%), viewing decision aids (37.4%), and finding the form very easy to understand (66.8%). Content of the training modules aligned well

Please address correspondence to Sarah Shoemaker, sarah_shoemaker@abtassoc.com.

Disclaimers. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does the mention of trade names, commercial products, or organizations imply endorsement by the US government. The authors assume full responsibility for the accuracy and completeness of the ideas presented.

Conflicts of Interest. All authors report no conflicts of interest.

ONLINE-ONLY CONTENT

See the online version of this article for Appendix 1. Literature Review. Appendix 2. Overview of Modules. Appendix 3. Pilot Test Hospital Characteristics. Appendix 4. Data Collection Methods.

with identified deficiencies. Barriers to completing the modules included staff turnover, competing demands, and lack of accountability. Facilitators included committed champions with available time, motivation, and release time for staff to take modules. Knowledge increased for leaders ($p < 0.05$) and staff ($p < 0.001$) who completed the training modules. Hospitals reported the effects of piloting the modules included fostering dialogue and identifying opportunities for improvements, identifying and rectifying policy ambiguity and noncompliance, reinforcing the use of interpreter services, and using modules' strategies and tools to improve informed consent.

Conclusion—Many opportunities exist for hospitals to improve their informed consent practices. AHRQ's two training modules, have face validity, addressed demonstrated deficiencies in hospitals' informed consent policies and processes, and stimulated improvement activity in motivated hospitals.

Informed consent in medical care is a process of communication between a clinician and patient that results in the patient's decision about whether to undergo a specific medical intervention. All too frequently, however, patients do not understand their options and associated risks and benefits, even after signing a consent form.[1] This situation is risky for patients, clinicians, and hospitals, as evidenced by informed consent–related patient safety events such as wrong-site surgery and other complications that are reported in The Joint Commission's Sentinel Event database.[2] Miscommunication during the consent process can also be costly, causing the delay or cancelation of tests, treatments, or procedures.[3,4]

Adequate informed consent requires being given complete, understandable information and recognizing that there is a choice, including the choice of not pursuing any medical intervention. Researchers have extensively documented the deficiencies of informed consent forms and processes and noted that low health literacy; language barriers; vision, hearing, and cognitive impairments; stress; and the complexity of medical interventions contribute to the difficulties in making informed decisions.[5–13]

Improving the informed consent process is possible. A recent Cochrane review of interventions to improve informed consent concluded, "Informed consent is most likely to be achieved when the patient has had a discussion with a clinician who is both well informed and skilled at providing information, and who uses interventions as described in this review to at least enhance patient knowledge."[14(p. 37)]

Overcoming the challenges to informed consent requires a systems approach to quality improvement (QI).[15] To provide hospitals with tools to help develop supportive infrastructure as well as build skills of clinical teams, the Agency for Healthcare Research and Quality (AHRQ) commissioned the development and pilot testing of two evidence-based training modules for improving informed consent in health care—one for leaders and one for health care professionals (HCPs)—titled *Making Informed Consent an Informed Choice*.[16] In this article we describe the results of pilot testing the modules in four hospitals to confirm the need for improved informed consent processes, to determine whether the modules increased knowledge about best practices, and to learn from hospitals' implementation experiences.

METHODS

Abt Associates' Institutional Review Board (IRB) and Ethical and Independent Review Services board and the US Office of Management and Budget (OMB #0935-0228) approved the data collection and analysis plan for this project.

Module Development Methods

We reviewed informed consent guides,[15,17] the peer-reviewed and gray literature,[9,15,18–23] and Joint Commission deidentified accreditation data and records of inquiries from hospitals (see Appendix 1, available in online article). We also formed an expert and stakeholder panel, consisting of experts in informed consent, health literacy, patient safety, risk management, and shared decision making, as well as a patient representative. (See Acknowledgements for a list of the expert panel members.) The literature review and the expert panel helped us identify 10 teachable best practices to ensure that the informed consent process provides an informed choice. It also helped us identify system changes, including policy improvements that support high-quality informed consent.

We developed two training modules that run on a learning management system—one for hospital leaders and one for HCP staff (clinicians and other HCPs, such as nurses). (For module outlines, see Appendix 2, available in online article.) *Making Informed Consent an Informed Choice: Training for Leaders and Health Care Professionals* includes interactive components and each take up to two hours to complete. A knowledge test is administered both at the start and the end of each module.

Hospital Recruitment and Selection

Hospitals were recruited through e-mail announcements to subscribers of AHRQ's health literacy and cultural competence updates and to approximately 50 hospitals that had previously worked with The Joint Commission on a research project. A primary selection criterion was readiness for change, defined as motivation and self-assessed capability.[24,25] Participation requirements included having an identified hospital liaison, available time, and willingness to participate in data collection activities. Of the 8 candidates identified, we purposively selected 4 hospitals with differing characteristics (for example, academic affiliation, patient population, size, location).[26] (See Appendix 3, available in online article, for details on participating hospitals.) One of the 4 hospitals dropped out of the pilot test before staff were able to complete the training module due to the departure of several key staff members who had championed the pilot test.

Data Collection

We used mixed methods to study baseline conditions and hospitals' approaches to launching the training modules. We collected the following data:

- Cross-sectional survey of leaders and HCP staff (included clinicians and other HCPs) in units slated to take the training modules on attitudes toward informed consent and informed consent practices (collected at up to two time points using online surveys, with paper surveys as an option)

- Cross-sectional survey of a convenience sample of patients at up to two time points from each of three hospitals that remained in the pilot until its end on the quality of the informed consent discussion and form (collected using paper surveys)
- Data on hospital experiences in implementing the modules and their impact on hospital improvement efforts:
- Collected during baseline and regular check-in call interviews with hospital liaisons and, in some cases, unit leaders every month for six to nine months
- Collected at on-site visits from individual and group in-person interviews
- Data from the modules' pre- and posttests

See Appendix 4, available in online article, for further details on additional data collection methods and instruments.

Analysis

Qualitative Analysis—We analyzed transcripts from telephone interviews, check-in calls, and site visit interviews using a content analysis approach. We used NVivo 10 (QSR International [Americas] Inc., Burlington, Massachusetts) to code transcripts using an initial codebook developed based on the interview protocol topics, adding additional codes and subcodes for themes that emerged during analysis. We used the coded text to write narrative descriptions of the experiences of each hospital, and produced a cross-case analysis[27] of the experiences across the four hospitals.

Analysis of Survey Data—We used Stata 13.1 (StataCorp LP, College Station, Texas) to analyze pooled data from all hospitals that collected leader, HCP, and patient survey data. Missing responses, responses of "don't know," and responses of "not applicable" were treated as missing values. We calculated the percentage of leaders (liaisons, hospital leaders), clinicians (physicians, independent physician assistants, and independent nurse practitioners and other HCPs [for example, nurses]) who "strongly agreed" or "agreed" with attitudinal statements about informed consent. We conducted chi-square tests to assess the statistical significance of differences between each type of respondent for each attitudinal statement. We used the same approach to assess the statistical significance of differences for each of the informed consent best practices, having calculated the percentage of clinicians and other HCPs who reported that they or their colleagues "always" or "usually" followed the practice. Most questions for the patient survey were binary (Yes/No), and we calculated the percentage of patients who answered "Yes." For the remaining questions we used a "top-box" approach of calculating the percentage with the most positive response.

Training Modules Pre- and Posttest Analysis—We used Microsoft Excel 2010 (Microsoft Corp., Redmond, Washington) to conduct a one-tailed t-test of paired sample means to determine the significance of differences between the pretest and posttest scores.

RESULTS

We report on the informed consent attitudes and practices at pilot hospitals, hospitals' experiences with launching the modules, and the impact the modules had on trainees' knowledge and on hospitals' efforts to improve informed consent. Finally, we describe how feedback from pilot hospitals was used to refine the modules.

Attitudes

Table 1 shows responses by leaders and clinicians to survey statements about attitudes regarding informed consent. The statements are grouped into those for which agreement is consistent with the principles of informed choice and those for which agreement is not consistent with those principles. Most clinicians who conduct informed consent discussions agreed with statements that are consistent with offering an informed choice and did not agree with statements that were not consistent. However, 20% of clinicians did not think that lack of patient understanding posed a serious patient safety problem. Furthermore, 45% of clinicians agreed with the statement—which is not consistent with informed choice principles—that clinicians are in a better position than patients to decide what patients need.

Although the difference between clinicians' attitudes and leaders' beliefs about clinicians' attitudes was significant for only two items, in part due to small sample sizes, leaders were less likely to think that clinicians held attitudes that were consistent with providing an informed choice than the attitudes actually reported by clinicians.

Informed Consent Practices

Reports of informed consent practices came from three sets of respondents: (1) hospital liaisons and leaders, (2) HCPs, both clinicians who conduct informed consent discussions and other HCPs, and (3) patients. These reports were collected from surveys and qualitative interviews, and the results from each are presented below. All respondents indicated that there was substantial room to improve informed consent practices.

Baseline Interview with Hospital Liaisons and Leaders Results—At baseline, hospital liaisons and leaders outlined a number of challenges to the informed consent process that demonstrated a need for improvement. One hospital liaison shared that physicians expressed no need for a substantive discussion with patients and therefore did not set aside time in the work flow for such. Another liaison reported that the hospital discovered that clinicians were engaging patients in some aspects of the consent discussion after initial preparations for a procedure were completed, undermining a patient's ability to make an informed choice and decline a procedure.

Participating hospitals identified several areas for improvement. One hospital discovered gaps in compliance with respect to completion of consent documentation that raised questions regarding the adequacy of the consent discussions with patients. Another hospital shared that their consent policy was widely disliked by clinicians, who considered the policy confusing and insufficient in describing best practices of the consent discussion. A third hospital had begun training staff on best practices for informed consent and saw the pilot as an opportunity to more effectively reach clinicians.

Health Care Professional (HCP) Survey Results—Table 2 displays results from the HCP survey. The first column shows self-reports by clinicians who conduct informed consent discussions on their use of informed consent best practices. We compared the self-reports with clinicians' reports of the practices of their colleagues ("Other Clinicians") as well as with reports by other HCPs (for example, nurses) who do not conduct informed consent discussions.

For half of the best practices 90% or more of clinicians reported that they always or usually employed the practice. For two additional practices—engaging patients and eliciting goals and values—85% of clinicians reported always or usually using them. In contrast, a low proportion of clinicians reported always or usually using teach-back (that is, checking understanding by asking patients to describe in their own words what they were told) or using high-quality decision aids (40% and 55%, respectively). Clinicians consistently rated their colleagues as using each best practice less frequently than themselves, by an average of 11.7 percentage points. Although those differences were not statistically significant, we also found that HCPs who were not responsible for informed consent reported clinicians' use of informed consent best practices to be much lower than self-reports, a statistically significant difference for six of the practices.

Site Visit Interview with Health Care Professionals Results—Qualitative data indicate that one reason for these differences may be that much of the informed consent conversation takes place before the patient arrives at the hospital. As one orthopedic surgeon stated it, "As far as the morning of surgery, the consent process is pretty modest. You are confirming the site of the procedure and if there are any additional things to discuss. The hard-core discussion takes place well ahead of surgery."

Patient Survey Results—Table 3 shows the results of the patient survey. To many of the items, more than 90% of patients gave responses that were consistent with informed consent principles. The exceptions—or areas for improvement—included being asked to teach-back (58.4%), being told what might go wrong (73.0%), having other options described (54.9%), being shown a decision aid (37.4%), being asked what matters most (68.6%), and finding a form very easy to understand (66.8%). While almost all reported they were encouraged to ask questions, 10.1% had unanswered questions—approximately half because they didn't get a chance to ask their questions, and half because they didn't get a satisfactory answer to questions asked. Less than two thirds were very satisfied with the informed consent experience.

Training Modules Rollout

Table 4 summarizes the number of leaders and HCP staff (clinicians and other HCPs) who were trained at each hospital. Pilot hospitals faced a variety of challenges in getting leaders and HCPs to take the two training modules. Barriers included the following:

- **Staff turnover.** Leaders at all hospitals described the rate of nurse turnover as a significant setback to maintaining the pilot's momentum. Two hospitals experienced substantial leadership turnover. As mentioned above, the departure

of the liaison and extensive turnover in key leadership positions at one hospital derailed the project entirely.

- **Competing demands.** Other high-profile efforts competed for staff's attention. These included delayed rollouts of new electronic health record systems and unscheduled Joint Commission survey visits.
- **Lack of accountability.** There were no consequences for failure to take the training. This was particularly an issue with nonemployee physicians, over whom hospitals had little leverage.

Facilitators to getting leaders and HCP staff trained included the following:

- **Committed champions with available time.** If a hospital's liaison took a passive approach or was overcommitted with other duties, fewer staff got training. Training numbers increased when committed champions tracked progress and actively encouraged staff to take the training. Strategies included repeatedly visiting participating units and enlisting assistance of other staff—including nurse educators and physician leaders— to encourage taking the training.
- **Supplying motivation.** Two sources of data were used to motivate staff. The first was recent internal or external reviews of informed consent processes that indicated the need for improvement, such as citations for inadequate informed consent processes by The Joint Commission. The second was data on attitudes about informed consent and use of best practices collected for the pilot, which at one hospital was presented at physician staff meetings to motivate engagement.
- **Providing staff release time to take modules.** More staff completed the training modules at one hospital than at the other three hospitals combined. That hospital's provision of release time to complete the training, the only hospital to do so, appears to have been helpful in getting staff to complete the training within the requested time frame.

Training Modules' Impact on Trainees' Knowledge

As shown in Table 4, across the four hospitals 28 leaders and 96 HCPs took the training modules (and completed the pre- and posttests). To assess learning resulting from the modules, pretest scores were compared to posttest scores for each of the learning modules. There was a statistically significant improvement ($p < 0.05$) in the posttest scores over the pretest scores for the 28 individuals who completed the leaders training module and quiz, with an average score of 74.1% posttest and 67.4% pretest. There was a statistically significant improvement ($p < 0.001$) in the posttest scores over the pretest scores for the 96 individuals who completed the HCP training module and quiz, with an average of 67.9% and 57.7%, respectively.

Training Modules' Impact on Hospitals' Improvement Efforts

Within a few months of training deployment, each of the three hospitals that remained in the pilot began to build momentum toward making policy changes and garnering the necessary

support to improve informed consent practices. These hospitals reported that the effects of piloting the modules included the following:

- Fostering dialogue and identifying opportunities for improvements. The training modules raised awareness about the state of informed consent processes in the hospitals. As one hospital liaison put it, “I think the most significant, consistent, and lasting [impact was that] it spearheaded dialogue.” Legal, compliance, ethics, and clinical staff, along with hospital administrative leadership, came together to discuss needed improvement in policy, consent forms, assessing patients’ capacity to consent, documentation, and other issues. When it was acknowledged that informed consent needed improvement, preoperative nurses were able to voice concerns. For example, after meetings with nursing staff, one hospital liaison stated, “Nurses [had been] looking at those consents, and dealing with those patients, and feeling that maybe they didn’t get the kind of discussion that they needed to make that decision. I think they felt a little bit like they couldn’t make that change themselves, and so they were looking for an opportunity, a project, something that could validate that they had these concerns.”
- Identifying and rectifying policy ambiguity and non-compliance. After training began, disparate views about who was allowed to do certain tasks in the informed consent process came to light. For example, there were disagreements as to whether residents or physician assistants were allowed to hold the consent conversation if they were not the person conducting the procedure. One hospital discovered that a large surgical group was not following the hospital’s policy of requiring signed informed consent forms before the day of scheduled surgery and worked with the group to resolve the problem.
- Reinforcing the use of interpreter services. Two hospitals discovered that some staff were not fully aware of, or had not been using, the available interpreter services. In addition, staff—including clinicians— acknowledged that they had previously used family members to interpret and that they used a qualified medical interpreter only if they thought there was a problem, despite knowing this was against hospital policy. The hospitals reported that best practices outlined in the module for using interpreter services reinforced their policies, and one hospital retrained staff on the language assistance policy and resources.
- Using modules’ strategies and tools to improve informed consent. Hospitals identified specific strategies and tools from the modules as being helpful. For example, one hospital liaison used the Policy Worksheet in the Leader Module to update its policy. At the same hospital, senior leadership approved of a new general consent form that had been revised using guidance from the Leaders Module. In another hospital, the CEO was moved to authorize a work group to review the hospital’s informed consent policy. Hospitals focused more on the strategies in the Leaders Module rather than on the shared decision-making strategies in the HCP module. However, hospitals were also interested in teach-

back and removing language barriers, as well as documentation and confirmation of consent.

One compliance staff person and liaison to the pilot summed up the modules' impact by saying, "When I hear language from the physician leaders that sort of mirrors material that was in the training, I know that it's sunk in and it's brought [informed consent] to the fore."

Refining the Modules

Interview data indicated that the modules provided pertinent, well-presented content. The modules, however, were too long (up to 150 minutes), and staff expressed frustration with the forced sequencing feature that required engaging every interactive element. Based on this feedback, we shortened the modules and removed the enforced sequencing feature, making the time to complete approximately 90 minutes. Data revealed that some questions were answered correctly by all trainees in the pretest, and some questions were answered incorrectly by the vast majority of the trainees in the posttest. The pretest analysis led us to replace some questions with ones that more appropriately measured the knowledge acquired from the modules, while the posttest question analysis led us to raise the visibility of certain content in the module and clarify some questions.

DISCUSSION

Our study reveals that there were substantial opportunities to improve informed consent policies and practices at the four pilot hospitals. For example, by their own admission, the majority of clinicians did not use teach-back and decision aids most of the time. Called an "always event" by the Institute for Healthcare Improvement,[28] teach-back has demonstrated beneficial effects,[22,29–32] and the National Quality Forum declared teach-back in informed consent a safe practice.[33] Furthermore, it appears that clinicians are apt to exaggerate their use of best practices, which may reflect a social desirability bias. Clinicians' reports of their colleagues' behavior, and other HCPs' reports, may be more accurate. Patient reports also indicate that clinicians may be overstating their conformance to the principles of informed consent. For example, only 55% of patients said that other options were described to them, in contrast to the 95% of clinicians who said they offered options.

Patient reports indicate that improvement in these and other areas would be valued by patients. More than a third of patients were not very satisfied with their experience, although patients may have reported a higher level of satisfaction had they not been asked about various elements of informed consent at the same time. Possible drivers of dissatisfaction may be the areas identified as areas for improvement in the summary of Table 3, or may be concerns not included in our survey. Even positive patient reports may be misleading, as they could be influenced by expectations. For example, the high proportion who said they had enough information may be reflecting the expectation that additional information would not be understandable.[34]

Clinicians' attitudes give clues as to why there are deficiencies in the informed consent process. The 45% of clinicians who thought they are in a better position than patients to decide what patients need may be more likely to push their own recommendations

paternalistically rather than offer patients real choices and help them decide which option is most consistent with their goals and values. The 20% of clinicians who did not think that lack of patient understanding was a patient safety problem would be unlikely to engage in practices—such as teach-back—aimed at ensuring patient understanding.

Pilot hospitals validated the content covered in the *Make Informed Consent an Informed Choice* modules as areas that hospitals could use support in improving. Although the modules increased knowledge among leaders and staff alike, hospitals—in rolling out the modules—ran into difficulties that QI projects often experience. As noted above, providing release time to take the modules was a facilitator to training completion. Other approaches to ensuring workforce preparedness should also be explored, such as integrating components of the HCP module into patient safety or new-employee education programs or as part of credentialing for physicians to have hospital privileges, as considered by one of the pilot hospitals. Other possible approaches include requiring the training as a nursing and physician competency, and linking the initiative with ongoing improvement efforts, such as improving the patient experience.

Despite the short implementation time frame, pilot hospitals made inroads to improving their informed consent processes and practices. They were able to begin improving their infrastructure, such as policy, forms, and language access, while HCPs were trained and units decided which best-practice strategies to adopt. There were several lessons learned for other hospitals to consider when implementing the training modules and pursuing improvements to informed consent[35]:

- Use a formal QI process (determine goals, timeline, and measures for monitoring).
- Recruit change leads, executive sponsors, and champions from key departments (for example., safety, compliance) and hospital units.
- Assess existing informed consent policies, practices, and work flow. Expect potential self-report biases.
- Engage staff in taking training, and reinforce training after it has been completed.
- Phase in implementation of selected strategies.

This study should be interpreted in light of its limitations. This pilot test was conducted in four hospitals that volunteered to participate in the demonstration project; therefore, findings are not generalizable. Because the pilot hospitals did not reach the stage of widespread implementation of module strategies, and one hospital dropped out before full implementation of the training modules, our study is unable to demonstrate whether the modules can change clinician attitudes and behavior. The sample sizes for the data collection efforts, including the number of staff trained, were small and not of comparable sizes across participating hospitals. The response rate for the HCP survey was an average of 77% at baseline, although the sample sizes were small in three of the four hospitals, which might not be representative of the staff's perspective. Leaders' and clinicians' responses to surveys likely indicated some social desirability bias, given that clinicians consistently rated their colleagues as using each best practice less frequently than themselves, for example.

Similarly, the patient surveys used small, convenience samples selected by hospital staff or the liaison, which may have introduced some selection bias. In addition, we did not capture which procedure patients were making a decision about, which may have influenced the informed consent process. It is difficult to discern whether the observed effects were the result of the training modules and implemented strategies or the result of participating in the pilot test, or a combination thereof.

We acknowledge that the type of procedure may influence the informed consent process; unfortunately, we were unable to systematically assess differences between procedures despite there being common procedures performed in the participating units (for example, obstetrics/gynecology procedures largely included vaginal or cesarean births and have a long lead time to go over risks, benefits, and so forth). The patient survey was not provided in languages other than English, which limits the extent to which non-English-speaking patients were represented and whose experiences may differ from those patients surveyed.

In addition to the limitations of this study, we acknowledge the limitations of the training modules.To keep the modules a manageable length, we could not go into sufficient depth to confer proficiency in all the topics covered. For example, the modules discuss determining patients' capacity for decision making but do not provide detailed guidance on how to conduct assessments of cognitive status. However, the resource sections of both modules provide references to more in-depth information and training.

CONCLUSION

Our study showed that the AHRQ's *Making Informed Consent an Informed Choice* training modules have face validity. They address demonstrated deficiencies in hospitals' informed consent processes and have stimulated improvement activity in motivated hospitals. Both 90-minute modules are available from AHRQ, and individuals affiliated with organizations accredited by The Joint Commission can earn 2 CE credits.[16,36] Within 10 months of modules' availability, 2,327 individuals had taken the Leaders Module, and 2,757 had taken the HCP Module. In addition, some organizations have acquired the modules to run on their own learning management systems. The modules appear to be meeting a need for practical tools to help hospitals improve their informed consent processes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors acknowledge Suzanne Miller Halegoua and Linda Fleisher as key contributors to the training module development, and Sean McClellan for his work on the survey analyses. They also would like to thank the expert panel who helped to shape the training modules and the pilot test design by providing guidance and feedback at critical points in the study: Mary Ann Abrams, David Andrews, Ellen Fox, Barbara Giardino, Yael Schenker, Faye Sheppard, Jana Towne, Dale Collins Vidal, and Matthew Wynia. Finally, they would like to thank the four participating hospitals and their liaisons for their arduous efforts getting their staff trained and striving to improve their hospital's informed consent practices, and without whom this study would not be possible.

Funding. The information upon which this publication is based was performed under Contract #HHSA290201000031I, TO #3, "Improving Hospital Informed Consent with an Informed Consent Toolkit," funded by the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

References

1. Brezis M, et al. Quality of informed consent for invasive procedures. Int J Qual Health Care. 2008; 20:352–357. [PubMed: 18625699]
2. The Joint Commission. Informed Consent: More Than Getting a Signature Quick Safety No 21. Feb, 2016. Accessed Apr 13, 2018 https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf
3. Gardner LA. Health literacy and patient safety events. Pennsylvania Patient Safety Authority. 2016; 13:58–65.
4. National Quality Forum (NQF). Implementing a National Voluntary Consensus Standard for Informed Consent: A User's Guide for Healthcare Professionals. Washington, DC: NQF; 2005. Accessed Apr 13, 2018 http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=23590
5. Bickmore TW, et al. Using computer agents to explain medical documents to patients with low health literacy. Patient Educ Couns. 2009; 75:315–320. [PubMed: 19297116]
6. Krankl JT, et al. Patient predictors of colposcopy comprehension of consent among English-and Spanish-speaking women. Women's Health Issues. 2011; 21:80–85. [PubMed: 20833068]
7. Mystakidou K, et al. Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries. SAHARA J. 2009; 6:46–57. [PubMed: 19936406]
8. Paasche-Orlow MK, Taylor HA, Brancati FL. Readability standards for informed-consent forms as compared with actual readability. N Engl J Med. 2003 Feb 20.348:721–726. [PubMed: 12594317]
9. Institute of Medicine Health Literacy: A Prescription to End Confusion. Washington, DC: National Academies Press; 2004.
10. Paasche-Orlow MK, et al. Readability of consent form templates: a second look. IRB. 2013; 35(4): 12–19. [PubMed: 23926857]
11. Bottrell MM, et al. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. Arch Surg. 2000; 135:26–33. [PubMed: 10636343]
12. Lloyd A, et al. The role of risk and benefit perception in informed consent for surgery. Med Decis Making. 2001; 21:141–149. [PubMed: 11310947]
13. Paasche-Orlow, MK. The challenges of informed consent for low-literate populations. In: Schwartzberg, JG.VanGeest, JB., Wang, CC., editors. Understanding Health Literacy: Implications for Medicine and Public Health. Chicago: AMA Press; 2005. p. 119-140.
14. Kinnersley P, et al. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. Cochrane Database Syst Rev. 2013 Jul 6.(7):CD009445. [PubMed: 23832767]
15. Fleischer, L., et al. A Practical Guide to Informed Consent. Philadelphia: Temple University Health System; 2008. Accessed Apr 13, 2018 https://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage27.html
16. Agency for Healthcare Research and Quality. AHRQ's Making Informed Consent an Informed Choice: Training Modules for Health Care Leaders and Professionals. Dec, 2016. (Updated: Feb 2017.) Accessed Apr 13, 2018 https://www.ahrq.gov/professionals/systems/hospital/informedchoice/index.html
17. Rozovsky, FA. Consent to Treatment: A Practical Guide,. 4th. Riverwoods, IL: Aspen Publishers; 2012.
18. Brach, C., et al. Ten attributes of health literate health care organizations. Jun, 2012. Accessed Apr 13, 2018 https://nam.edu/wp-content/uploads/2015/06/BPH_Ten_HLit_Attributes.pdf
19. National Center for Health Statistics (NCHS). Healthy People 2010 Final Review. Hyattsville, MD: NCHS; 2012.

20. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion (ODPHP). National Action Plan to Improve Health Literacy. Washington, DC: ODPHP; 2010. Accessed Apr 13, 2018 http://www.health.gov/communication/hlactionplan/pdf/Health_Literacy_Action_Plan.pdf
21. Abrams MA, Earles B. Developing an informed consent process with patient understanding in mind. N C Med J. 2007; 68:352–355. [PubMed: 18183759]
22. Matiasek J, Wynia MK. Reconceptualizing the informed consent process at eight innovative hospitals. Jt Comm J Qual Patient Saf. 2008; 34:127–137. [PubMed: 18419042]
23. Schenker Y, et al. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. Med Decis Making. 2011; 31:151–173. [PubMed: 20357225]
24. Weiner BJ, Amick H, Lee SY. Conceptualization and measurement of organizational readiness for change: a review of the literature in health services research and other fields. Med Care Res Rev. 2008; 65:379–436. [PubMed: 18511812]
25. Wise CG, et al. Journey toward a patient-centered medical home: readiness for change in primary care practices. Milbank Q. 2011; 89:399–424. [PubMed: 21933274]
26. Patton, MQ. Qualitative Research & Evaluation Methods. 3rd. Thousand Oaks, CA: Sage Publications; 2002.
27. Yin, RK. Case Study Research: Design and Methods. 5th. Thousand Oaks, CA: Sage Publications; 2014.
28. Unity Point Health Always Use Teach-back! Home page. 2018. Accessed Apr 13, 2018 http://www.teachbacktraining.org/
29. Schillinger D, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med. 2003 Jan 13.163:83–90. [PubMed: 12523921]
30. Weiss, BD. Health Literacy and Patient Safety: Help Patients Understand Manual for Clinicians. 2nd. Chicago: American Medical Association Foundation; 2007.
31. Turner T, et al. Pediatricians and health literacy: descriptive results from a national survey. Pediatrics. 2009; 124(Suppl 3):S299–S305. [PubMed: 19861484]
32. Jager AJ, Wynia MK. Who gets a teach-back? Patient-reported incidence of experiencing a teach-back. J Health Commun. 2012; 17(Suppl 3):294–302.
33. Wu, H., et al. Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy: An Implementation Report. Washington DC: National Quality Forum; 2005. Accessed Apr 13, 2018 http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=22090
34. Langer, G. Building better healthcare for low-income Californians: results on shared decision making Presented at the. Institute of Medicine; Washington DC: Dec 6, 2013
35. Shoemaker, SJ., Brach, C. AHRQ Publication No 17-0061-1-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2017. Implementation Guide for AHRQ's Making Informed Consent an Informed Choice Training Modules. Accessed Apr 13, 2018 https://www.ahrq.gov/professionals/systems/hospital/informedchoice/informed-implementation-guide.html
36. The Joint Commission. Improving the Informed Consent Process in the Hospital Setting. 2017. Accessed Apr 13, 2018 https://www.jointcommission.org/informed_consent_process_training.aspx

Table 1

Agreement with Statements About Informed Consent: Clinicians' Attitudes and Leaders' Beliefs About Clinicians' Attitudes

Strongly Agree or Agree with the Following Statements	Attitudes of Clinicians Who Conduct Informed Consent Discussions (n = 20) %	Leaders' Beliefs About Clinicians' Attitudes (n = 26) %	Significant Difference Between Clinician & Leaders
Agreement Is Consistent with Informed Choice			
Clinicians should encourage patients to talk about their values.	90.0	73.1	
Clinicians are responsible for ensuring that patients understand all their options before making a decision.	90.0	92.3	
Lack of patient understanding of benefits, harms, and risks of treatments is a serious patient safety problem.	80.0	88.0	
The informed consent process is worth the time it takes.	100.0	76.9	*
Agreement Is Not Consistent with Informed Choice			
Clinicians should not present alternatives that are demonstrably less effective.	10.0	19.2	
Clinicians are in a better position than patients to decide what patients need.	45.0	50.0	
Refusing a life-saving treatment or procedure demonstrates that the patient is not capable of making a sound decision.	0.0	8.0	
Getting the patient's signature on a consent form is the most critical part of the informed consent process.	0.0	30.8	†
The chief purpose of the informed consent process is to comply with regulations and be protected from lawsuits.	5.0	20.0	

*$p \leq 0.05$.

†$p \leq 0.01$.

Note: *Clinicians* include physicians, independent physician assistants, and independent nurse practitioners who conduct informed consent discussions.

Table 2

Health Care Professionals' Perspectives on Use of Informed Consent Best Practices

Always or Usually Used the Following Best Practices	Clinician Self-Report of Practices (*n* = 20)	Clinician Report on Other Clinicians' Practices (*n* = 20)	HCP Report on Clinicians' Practices (*n* = 222)	Difference Between Clinician Self-Report & Report on Other Clinicians' Practices	Difference Between Clinician Self-Report & HCP Report on Clinicians' Practices
Assess patient's decision-making capacity	95.0	90.0	77.4	−5.0	−17.6
Allocate ample time in private space.	95.0	80.0	66.5	−15.0	−28.5*
Use health literacy universal precautions.	70.0	65.0	57.8	−5.0	−12.2
Call for qualified interpreter when patient speaks a different language.	95.0	85.0	71.2	−10.0	−23.8†
Offer choices, including the option of doing nothing.	95.0	80.0	61.8	−15.0	−33.2*
Engage patients, family, friends in the consent discussion.	85.0	60.0	70.6	−25.0	−14.4
Elicit goals and values.	85.0	65.0	58.2	−20.0	−26.8†
Encourage questions.	95.0	85.0	81.6	−10.0	−13.4
Neutrally explain benefits, harms, and risks of all options.	90.0	85.0	75.8	−5.0	−14.2
Use high-quality patient decision aids.	55.0	52.6	44.1	−2.4	−10.9
Use teach-back technique to check understanding.	40.0	30.0	47.3	−10.0	7.3
Document consent discussion.	75.0	50.0	39.3	−25.0	−35.7*
Ask patients to confirm consent immediately before test, treatment, or procedure when consent has been given in advance.	90.0	85.0	56.6	−5.0	−33.4*

*$p \leq 0.01$.

†$p \leq 0.05$.

Note: *Clinicians* include physicians, independent physician assistants, and independent nurse practitioners who conduct informed consent discussions. *HCP* refers to other health care professionals, such as nurses.

Table 3

Patients' Perspectives on Their Informed Consent Experience

	% (*n* = 234)
Explanation About the Test, Treatment, or Procedure	%
Yes, person explained what would likely happen	94.0
Explanation was "definitely" easy to understand	90.5
Yes, person asked patient to describe understanding of what would likely happen	58.4
Yes, person explained what might go wrong and how likely it was	73.0
Explanation was "definitely" easy to understand	85.5
Other Options	
Yes, person described other options, including *no* test or treatment as an option	54.9
Explanation was "definitely" easy to understand	80.6
Yes, someone showed patient a decision aid	37.4
Yes, decision aid was helpful in decision	77.4
Yes, felt free to choose any option, including choosing *no* test or treatment	92.9
Informed Consent Discussion	
Yes, person listened carefully	99.1
Yes, person spent enough time	96.9
Yes, person asked about what matters most	68.6
Yes, person encouraged patient to ask questions	96.0
Yes, I had unanswered questions	10.1
I asked, but I didn't get an answer	1.2
I asked, but response didn't answer my questions	3.7
I asked, but the response was hard to understand	2.4
There wasn't enough time to ask questions	4.9
I didn't feel that I could ask questions	1.2
Other	1.2
Had enough information	96.9
Satisfaction with the Discussion	
Yes, overall very satisfied with the experience	61.8
Consent Form	
Yes, form was in English and patient reads English very well, or it was in the patient's language (non-English) and they read their language very well	95.8
Form was "very easy" to understand	66.8

Note: 90% of patient surveys were completed by patients themselves, and 8.9% were completed by a parent, legal guardian, health care proxy, or family member or friend. Most respondents reported having the informed consent conversation with their personal doctor (52.4%) or a doctor from the hospital (28.1%). The vast majority did not use an interpreter for the discussion and indicated that they speak English very well (97.4%). Although a Spanish version of the survey was available, it was not used by the hospitals, which may have affected the representativeness of the results.

Table 4

Number of Staff Who Completed Training

	Hospital A (Northeast)	Hospital B (Northeast)	Hospital C (South)	Hospital D (Northwest)	Total
Leaders Trained	7	11	5	5	28
Staff Trained	15	73	7	1	96

Table D1 provides a summary of the data collection methods, respondents, research domains addressed by each method, and sample sizes. Hospital D dropped out six months into the pilot test due to the departure of several key staff involved in the project; the hospital was unable to complete the data collection efforts.