

**Automating the Shared Decision-Making Process –  
Lessons Learned/New Directions**

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## ABSTRACT

The Centers for Medicare and Medicaid Services (CMS), the Joint Commission, and statutes in each state require that treatments and procedures must be preceded by a process of shared decision-making. This communication process between a provider and patient is commonly referred to as the informed consent discussion. Organizations including the Agency for Healthcare Research and Quality, the Leapfrog Group, and the National Quality Forum have all determined that an effectively executed shared decision-making process significantly improves patient safety.

In 2004, the Department of Veterans Affairs (VA) announced its Electronic Support for Patient Decisions (ESPD) initiative – a program implemented across all VA medical centers to employ a software tool to assist providers with the informed consent process. Various VA medical centers have utilized novel strategies to further leverage the ESPD initiative. One of the most exciting opportunities involves use of the information obtained from the informed consent encounter during the preoperative verification and the operating room “time out” processes. Research suggests that significant patient safety benefits are obtained by employing the patient’s understanding of their planned procedure or treatment as an additional layer of protection against medical errors.

Patient safety organizations have advocated the use of “teach back” during the shared decision-making process as a means of enhancing communication and confirming understanding, particularly in patients with low medical literacy or with limited English proficiency. Strategies for electronically prompting, facilitating, and documenting the responses obtained when using “teach back” during the shared decision-making process are examined. In addition, preliminary findings accruing from a major investigation of this process are presented and discussed.

## SHARED DECISION-MAKING AND INFORMED CONSENT

### Shared Decision-Making – The Process

The term ‘shared decision-making’ is a relatively new construct that describes the collaborative evaluation of a patient’s condition and various treatment options by both the patient and his or her provider prior to cooperatively selecting a treatment course. This process is effectively what organizations such as the American Medical Association have outlined as the informed consent process – a communication process in which the provider and patients review the following:<sup>1</sup>

- The patient's diagnosis, if known
- The nature and purpose of the proposed treatment or procedure
- The risks and benefits of the proposed treatment or procedure
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance)
- The risks and benefits of the alternative treatment or procedure
- The risks and benefits of not receiving or undergoing the treatment or procedure

Unfortunately, “informed consent is often seen as a burdensome administrative practice that involves obtaining a signature on a form for the legal protection of physicians and institutions.”<sup>2</sup> As a result, some institutions have implemented strategies to ensure that the informed consent process remains a true decision-making endeavor. Examples of these strategies include efforts to formalize the shared decision-making process in centers that are dedicated to helping patients fully understand their treatment options<sup>3</sup> and programs to employ electronic tools to support patient decisions.<sup>4</sup>

### Applicable Standards and Requirements

Various organizations have sought to codify a hospital’s ethical responsibilities for ensuring appropriate interactions by providers in order to confirm that patients fully participate in decisions involving their care and treatment. Joint Commission standard RI.2.40 states that a hospital’s informed consent policy must describe the following:<sup>5</sup>

- The procedures that require informed consent
- The process used to obtain informed consent. Further, the informed consent process must include a discussion of the following elements:
  - Nature of the proposed treatment or procedure
  - Benefits of the contemplated treatment or procedure
  - Risks of the planned treatment or procedure
  - Likelihood of achieving goals
  - Alternatives to the proposed treatment or procedure, including the risks and benefits of the alternatives
  - Patient’s prognosis if treatment is declined

- Any limitations on the confidentiality of patient information
- How informed consent is documented
- When surrogate decision-makers may provide informed consent on the patient's behalf
- The circumstances under which care or treatment may be provided without obtaining informed consent (typically for emergent care)

Joint Commission has established other standards that ensure that patients receive sufficient information to make decisions. The requirements relevant to ensuring that the patient is educated about his or her treatment plan are enumerated in Standard PC.6.10.

The Centers for Medicare and Medicaid Services (CMS) has also established guidelines for the informed consent process. CMS charges state healthcare agencies with ensuring institutional compliance with Conditions of Participation (CoPs). CoPs are the minimum health and safety standards that hospitals must meet in order to participate in the Medicare and Medicaid programs. CMS publishes a State Operations Manual (SOP) that guides state surveyors on how to interpret the CoPs. In April 2007, CMS issued revised interpretive guidelines for informed consent for the first time in 3 years.<sup>6</sup> Those guidelines note that a well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used
- The indications for the proposed surgery
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity
- Treatment alternatives, including the attendant material risks and benefits
- The probable consequences of declining recommended or alternative therapies
- Who will conduct the surgical intervention and administer the anesthesia
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines
- Whether, as permitted by state law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital

Included in the revised interpretive guidelines are two new requirements that are of particular concern to hospitals:

<u>Requirement</u>	<u>Implication</u>
1. Hospitals must now ensure that the practitioners responsible for the surgery performed within the hospital obtain informed consent from patients in a manner consistent with the hospitals' policies.	For most procedures informed consent is best obtained well in advance of the treatment date and within the physician's office. Hospitals are now chartered with ensuring that those remote discussions comply with the hospitals' policies governing the informed consent process.
2. Surveyors are now charged with interviewing two or three postsurgical patients to see how satisfied they are with the informed consent discussion prior to their surgery.	The collection of patient feedback on the informed consent process means that hospitals must ensure that systems and practices are in place that patients will recognize as being beneficial.

## **PATIENT SAFETY**

### **Analyzing the Problem**

Publication of the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health System*, catapulted the issue of patient safety in health care to the forefront of public awareness. Comparison of the healthcare delivery system to other complex, dynamic, time-pressured, yet highly reliable organizations has proven to be one of the more thoughtful approaches to analyzing safety issues in health care. Two types of organizations with very low error incident rates include US nuclear power plants and air traffic control centers. These organizations have not approached error reduction with a "person approach", i.e. with efforts to reduce unwanted variability in human behavior. Rather, these high-reliability organizations have adopted a "systems approach" – an acknowledgement that some human error is inevitable and that defensive measures, such as policies and procedures that seek to avert error, are an effective approach to minimizing risk.

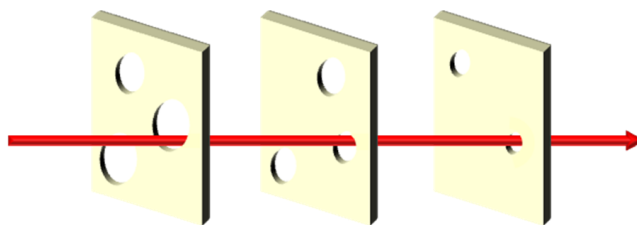
One means for modeling the systems approach to error prevention is the "Swiss Cheese Model."<sup>7</sup> This approach likens each defensive layer to a slice of Swiss cheese. If the holes in the slices of cheese, which are constantly moving and changing shape, momentarily line up, they permit a trajectory of accident opportunity (see Figure 1). This model suggests that efforts should be made to insert additional "slices of cheese," or additional safeguards, in order to avoid an error. When the problem of wrong-site/wrong-procedure/wrong-patient surgery is examined, it appears that significant emphasis is frequently placed on the "sharp end of the spear" – where the knife cuts the tissue. This approach is evident in the "Time Out" process outlined in the Joint Commission's Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery<sup>TM</sup>.<sup>8</sup> The "Time Out" process to verify the correct patient, procedure, and site is performed immediately prior to the start of the procedure. A complementary

approach is to focus upon the “blunt end of the spear,” or early opportunities for intervention, well prior to initiation of treatment. In this regard, leverage of the informed consent process might provide an excellent opportunity to implement an additional safeguard. The AHRQ Evidence Report, released in response to the concerns raised by the IOM report, noted that “informed patients are less likely to experience medical errors by acting as another layer of protection.”<sup>9</sup>

Figure 1

### Swiss Cheese Model

A trajectory of accident opportunity has penetrated the safeguards arranged to avoid an error.



### Informed Consent and Medical Error

There is ample evidence that attention to the shared decision-making process can prevent medical errors. It has been estimated that 45 percent of wrong-site surgeries could be eliminated simply by having a properly completed consent form.<sup>10</sup> A 30-month analysis of all reports of wrong-site surgery in the State of Pennsylvania found that successful recovery from a potential instance of wrong-site surgery was due most commonly to the patients themselves, followed very closely by verification of the consent form.<sup>11</sup> In spite of the evidence supporting the relationship between effective communication and avoidance of medical error, there remain significant opportunities for improvement.

A large study of 3,552 patient-decisions found that only 9 percent met the criteria for a fully informed decision.<sup>12</sup> A subgroup analysis of those same decisions found that only 0.5 percent of the complex decisions were fully informed. The presence of a written consent form may do little to indicate that an informed decision has been made. An analysis of 540 written consent forms from 157 hospitals found that only 26 percent of the documents contained the necessary elements of informed consent – the purpose, risks, benefits, and alternatives.<sup>13</sup> Similarly, the presence of a written consent form may not always result in appropriate care. A study of 89 patients undergoing radical prostatectomy found that 89 percent of those patients were advised of the risk of requiring supplemental blood products, yet the consent of those patients to receive blood products was documented in only 26 percent of the cases. A subsequent review found that 92 percent of the patients were ultimately transfused.<sup>14</sup>

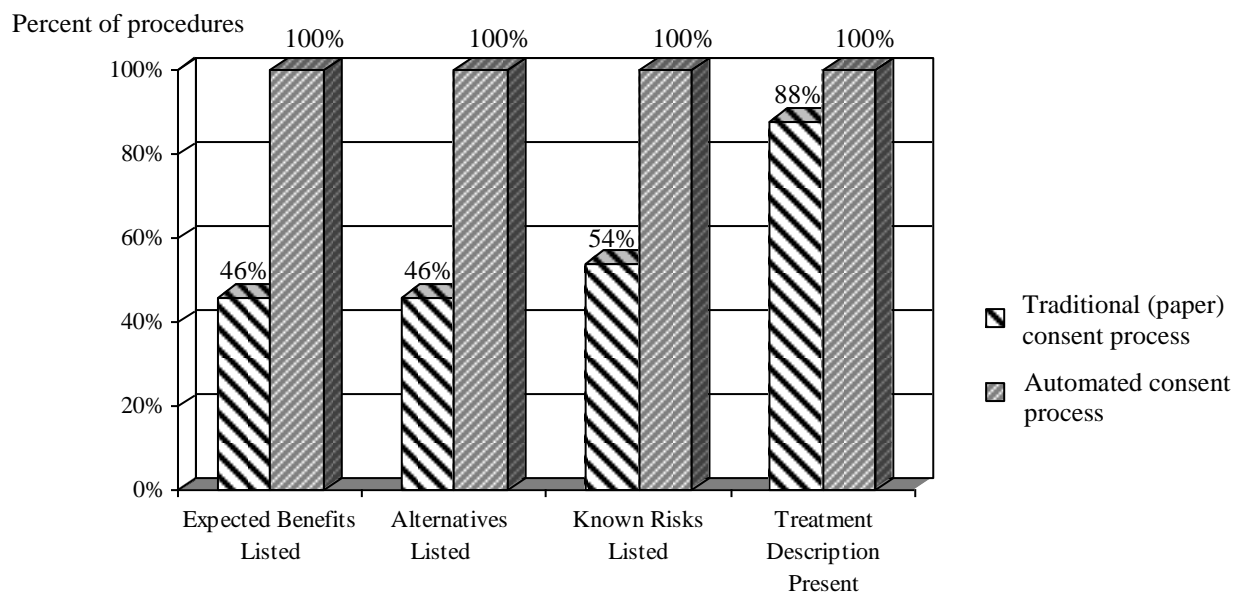
## VA EXAMPLE

### Electronic Support for Patient Decisions

Beginning in 2003, the Department of Veterans Affairs (VA) National Center for Ethics in Health Care began an evaluation of potential software solutions, aiming to standardize the informed consent and patient decision-making process. After a pilot program conducted in 5 VA medical centers, the VA selected an electronic tool, the iMedConsent™ application (Dialog Medical, Duluth, GA), which was deployed across all 158 VA medical centers in late 2004 and early 2005 as part of the Electronic Support for Patient Decisions (ESPD) initiative.<sup>15</sup>

As part of the pilot program, extensive data was collected comparing the traditional paper-based informed consent process to the computer-assisted process in two large VA medical centers (VAMCs), the Atlanta VAMC and the Hines VAMC in Chicago. The expected benefits, key risks, and practical alternatives were found to be missing from approximately one-half of the paper-based consent documents. Those same critical elements were present in all of the consent forms generated by the automated informed consent solution (see Figure 2).

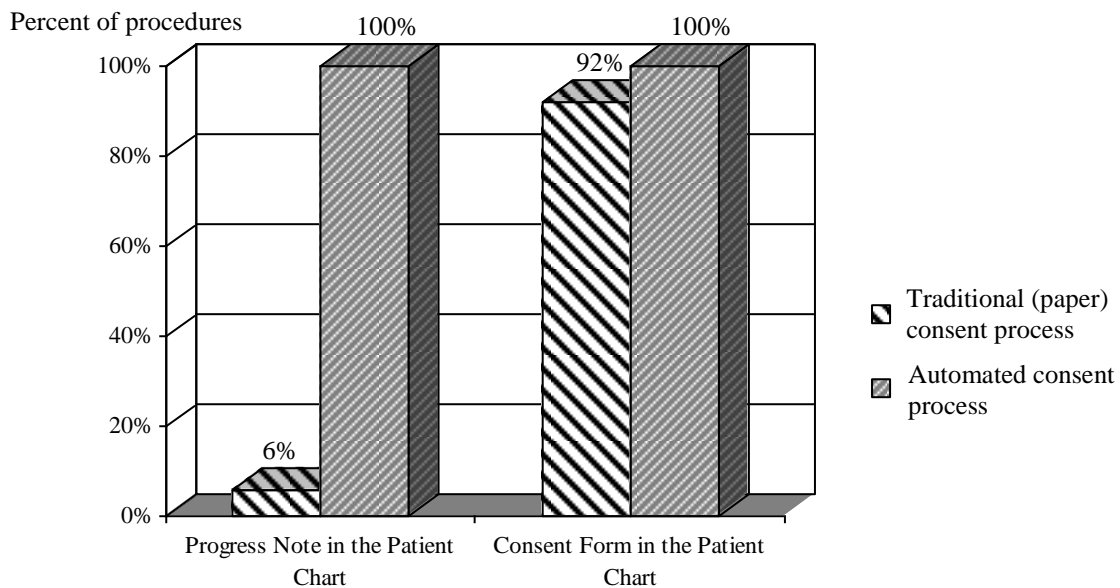
Figure 2  
**Study of Traditional vs. Computer-Assisted Decision-Making**  
(Conducted in two VA Medical Centers)



Source: O'Hara R. Electronic Support for Patient Decisions: Automating and Integrating the Informed Consent Process. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

Clearly, in order for providers to leverage the informed consent process as a means of enhancing patient safety, an informed consent form and/or a note in the patient’s medical record confirming completion of the consent process must be available. The previously mentioned study in 2 VAMCs also found that use of the electronic informed consent process ensured that both notes and signed consent forms were always present in the patient’s medical record (see Figure 3).

Figure 3  
**Study of Traditional vs. Computer-Assisted Decision-Making**  
 (Conducted in two VA Medical Centers)



Source: O’Hara R. Electronic Support for Patient Decisions: Automating and Integrating the Informed Consent Process. Presented at the 21st Annual TEPR Conference, Salt Lake City, May 17, 2005.

Not surprisingly, the use of an automated informed consent application within VAMCs has been essential to ensuring successful Joint Commission surveys. The ability of any member of the patient’s care team to access an informed consent document is crucial to satisfying surveyors who employ a tracer methodology when performing a hospital audit.<sup>16</sup>

### LEVERAGING INFORMED CONSENT

#### Time Out

With details from the informed consent discussion collected and documented electronically, information can be readily accessed to improve patient safety. The electronic informed consent application employed by the VA not

only ensures that all required elements for a shared decision-making process appear on the consent form; it also automatically imports those key elements into a progress note that is placed in VistA CPRS, the electronic health record employed by the VA. The documentation of the patient's name, the planned procedure or procedures, and the planned surgical sites is thus prominently available, not only as a digital image of the signed consent form, but also in a note that can be summoned virtually instantaneously for review by any member of the care team. In many facilities, review of this information during the "Time Out" process is not a new practice. However, the information from traditional paper-based forms may be incomplete,<sup>13</sup> illegible,<sup>14</sup> or unavailable.<sup>17</sup> In the VA health system, the electronic note containing that vital information is always readily accessible and legible. Some VA medical centers have revised their preoperative "Time Out" process to require the use of the automatically generated note to confirm the presence of the correct patient, the correct procedure, and the correct surgical site.<sup>18</sup>

## CONFIRMING PATIENT COMPREHENSION

### Repeat-Back

Safe Practice 2 of the National Quality Forum (NQF)-endorsed<sup>TM</sup> Safe Practices for Better Healthcare addresses the critical practice of informed consent. Specifically, Safe Practice 2 states:

*Ask each patient or legal surrogate to "teach back" in his or her own words key information about the proposed treatments or procedures for which he or she has been asked to provide informed consent.*<sup>19</sup>

The NQF has recommended that the "teach back" or "repeat back" process ensure that patients can explain:

- The diagnosis for which they need care
- The treatment, service or procedure
- Risks of the treatment or procedure
- Benefits of the treatment or procedure, and
- Alternatives to the proposed treatment or procedure

The NQF has also laid out "Strategies for Progressive Organizations," which include the recommendation that evidence of the "teach back" or "repeat back" process be documented on the consent form itself or in the patient's healthcare record prior to performing the procedure.

### Automating "Repeat Back"

An automated informed consent application provides an ideal vehicle for assisting providers with the "repeat back" process. One such application prompts the provider to ask the five NQF-recommended questions above plus an additional sixth question concerning the surgical site. Those six questions, employed to confirm patient comprehension of the shared decision-making process are:

1. Describe the diagnosis or health problem for which you need care.
2. Describe in your own words what will be done to you.

3. Describe where on your body the treatment or procedure will be performed.
4. Describe in your own words how this treatment or procedure will benefit you.
5. Describe what you consider to be the major risks associated with this procedure.
6. Describe the alternative treatments and procedures available to you.

An automated informed consent application can also assist the provider with documenting the patient's responses to "repeat back" inquiries and automatically summarize their responses in the patient's healthcare record.<sup>20</sup>

## EVALUATING "REPEAT BACK"

### Studies Involving "Repeat Back"

Although the NQF has suggested that adding "repeat back" to the informed consent process will improve comprehension, the studies assessing this practice have been relatively small observational studies. In one study, investigators evaluated the impact of "repeat back" on the consent process for patients scheduled for a percutaneous lung biopsy. In this study, "repeat back" was continued until the patients were able to recite all the relevant risks of the procedure. The authors noted a large improvement in comprehension (38 percent correct in the usual care group compared with 66 percent correct in the "repeat back" group).<sup>21</sup> In another small study of 20 patients undergoing anterior cruciate ligament reconstruction, use of "repeat back" improved comprehension of risks and benefits from 74 percent to 100 percent.<sup>22</sup> The effect of employing "repeat back" during clinicians' encounters with low health-literacy diabetic patients was evaluated in another study. For the patients with hemoglobin A<sub>1c</sub> levels below the mean for the group, there was strong indication that those patients' physicians had assessed recall and comprehension compared to the physicians who did not (odds ratio 15.15, P<0.01).<sup>23</sup> The recent development of a module that supports "repeat back" within an automated informed consent software application affords researchers the opportunity to test this additional practice's impact upon the standard informed consent discussion in a more controlled manner and with a significantly larger population of potential subjects.

### VA Study

In November 2005, VA's Health Services Research and Development Service (HSR&D) awarded a grant to initiate the first large-scale, multicenter study of the "repeat back" technique during the shared decision-making process. The study is titled: "Benefits of 'Repeat Back' Protocols within a Computer-Based Informed Consent Program." The hypothesis of the study is that use of the an enhanced automated informed consent software application with "repeat back" (iMedConsent™ application, Dialog Medical, Duluth, GA), will improve the surgical patient's comprehension about the surgical technique, treatment alternatives, and risks and benefits of the proposed surgery in comparison with the standard informed consent process. The investigators further hypothesize that this enhanced program will also lead to better patient satisfaction with the consent process, decision making, and the health care received, as well as less anxiety about the operation. They also expect that this program will be acceptable to surgical providers and may potentially lead to better clinical outcomes.<sup>24</sup>

The principal investigator of the study is Aaron Fink, MD and the co-principal investigator is Allen Prochazka, MD, MSc, both with the VA. The study consists of a multicenter, randomized trial that is being conducted in 7 VA medical centers (Atlanta, Cincinnati, Denver, Houston, Pittsburgh, Portland, and Tampa). The study compares the use of the “standard” consent process, as outlined by the VA’s ESPD initiative, and the “enhanced” process that adds the “repeat back” procedure facilitated by the automated informed consent application. The protocol proposes enrollment of 600 subjects scheduled for elective surgery. The surgical procedures to be studied include: carotid endarterectomy, total hip arthroplasty, radical prostatectomy, and laparoscopic cholecystectomy. Subjects are individually randomized to the “standard process” or to the “enhanced process.” In addition, the study data will be linked with the National Surgical Quality Improvement Program (NSQIP) data, which will provide baseline data on patient characteristics and intraoperative variables, as well as data on 30-day risk-adjusted surgical outcomes. The endpoints assessed include: patient comprehension, patient satisfaction with the consent process, patient anxiety, provider acceptance of the informed consent process, patient satisfaction with health care and with decision-making using validated self-report survey instruments, and time spent during the informed consent process.

The first interim statistical analysis was completed for the study’s Data and Safety Monitoring Board on October 4, 2007. As of that date, 335 patients had been enrolled in the study and data entry had been completed for 67 subjects. A comparison of the patients randomized to the 2 arms of the study shows good similarity between the groups (see Table 1).

Table 1

**Patient Characteristics between Arms in the “Repeat Back” Study**

	Repeat-Back [n = 35]	Standard [n = 32]
<u>Characteristic</u>	<u>Mean (SD)</u>	<u>Mean (SD)</u>
Age	60.91 (13.70)	62.74 (9.84)
SF-12* (physical)	42.69 (13.07)	35.54 (11.64)
Median Norm for VA Patients 55-64 years of age is 50		
SF-12* (mental)	54.51 (12.71)	50.73 (13.53)
Median Norm for VA Patients 55-64 years of age is 54		
STAI** (anxiety - visit 0)	1.58 (0.68)	1.91 (0.91)
REALM***	60.65 (9.27)	62.61 (4.21)

≥60 corresponds to a high school reading level

\*12-item Short-Form health survey

\*\*State-Trait Anxiety Inventory measuring instrument

\*\*\*Rapid Estimate of Adult Literacy in Medicine assessment tool

Providers worry that employing “teach back” or “repeat back” during the informed consent process may significantly lengthen the time required with the patient. A preliminary analysis of the data from the first 67 patients indicates that the incremental time may not be dramatic (see Table 2). Furthermore, the time difference between the 2 practices is perhaps less significant than the variability in the time required to complete the informed consent process, which may be site-dependent. Table 2 presents both the aggregate values and the values reported by the site that spent the longest time with each patient (Denver) and the site that spent the shortest time with each patient (Houston).

Table 2  
**Time Spent Completing the Informed Consent Process (Minutes)**

<u>Site</u>	<u>n</u>	<u>Repeat-Back</u>		<u>Standard</u>	
		<u>minutes (SD)</u>	<u>n</u>	<u>minutes (SD)</u>	<u>n</u>
All Sites	35	14.58 (12.3)	32	8.81 (5.7)	
Denver	8	33.37 (21.71)	6	12.17 (4.62)	
Houston	15	9.13 (4.09)	15	5.00 (1.89)	

We anticipate that the “Benefits of ‘Repeat Back’ Protocols within a Computer-Based Informed Consent Program” study will be of great interest to the VA and also to patient safety researchers who are proponents of the “repeat back” practice.

## CONCLUSIONS

There is a critical relationship between patient safety and shared decision-making as evidenced by research into the mechanisms for avoiding wrong-site surgery. A process-oriented approach to improving patient safety suggests that the informed consent process may be leveraged as an additional layer of protection (or “slice of cheese” in Reason’s model) in the avoidance of medical error. Providing automated tools to assist with this critical process helps to standardize the process and ensure that it is employed consistently and universally within a healthcare facility. Efforts such as the VA’s ESPD initiative have been shown to dramatically improve documentation of the informed consent process. Leveraging technology further ensures that the documentation is readily available to providers in their efforts to prevent wrong-patient/wrong-procedure/wrong-site surgery.

New directions, such as changing hospital processes to formally integrate the information obtained during the shared decision-making process into the OR “time out” process, may help improve patient safety. Likewise, research into the NQF-endorsed “repeat back” process may provide healthcare organizations with additional direction as to how to further enhance the critical process of shared decision-making.

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