Shared Decision Making in Surgery to Improve Patient Safety and Reduce Liability

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9/1/2010-8/31/2012
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We acknowledge the support of a grant from the Agency for Healthcare Research and Quality (AHRQ R21 HS19532).

ABSTRACT

Purpose: Physician-patient miscommunication with inadequate risk communication in the informed consent process contributes to patient dissatisfaction, complaints, and medical liability associated with surgical procedures. The aims of this project were to develop shared decision-making aids; evaluate patient and provider barriers to implementation of shared decision making; implement shared decision-making in spine surgery; measure quantity, quality, and costs of patient complaints and risk management transactions; and evaluate patient satisfaction and provider informed consent process before and after implementation of shared decision making.

Scope: UW Medicine, orthopedic spine surgery, anesthesiology

Methods: We developed anesthesia decision aids using International Patient Decision Aid Standards Collaboration criteria and we created a patient activation brochure. We evaluated provider performance of shared decision making by patient survey and scoring audiotaped clinical encounters. Risk management resources were compared by estimated time and costs for processing patient complaint and medical error files.

Results: Anesthesia decision aids were revised after broad stakeholder feedback. The patient activation pamphlet was implemented. A shared decision-making training toolkit was developed. The most challenging elements of shared decision making were establishing the patient role, encouraging patients to seek input, eliciting patient preferences, and assessing patient understanding. Informed consent accounted for 41% of total risk management files. Resource consumption for patient complaints was similar to medical error resolution. Implementation of shared decision making into clinical practice is challenging yet has potential to significantly reduce liability and previously unappreciated hidden costs associated with deficiencies in informed consent.

Key words: Shared decision making, informed consent, liability, patient decision aids

Introduction

Informed consent is an ethical obligation of the practice of medicine and a legal requirement per statute and case law in all 50 states. It requires a thoughtful dialogue between physician and patient wherein "sufficient information" is imparted so that the patient can make an educated decision with respect to the medical treatment proffered. Unfortunately, physicians often do not share the information patients need to make an informed decision. Physicians frequently discuss the nature of the procedure, but risks/benefits are less frequently discussed, and patient understanding is rarely assessed (Braddock, 1997). In many cases in the surgical arena, the informed consent discussion is even more limited, with mere signing of the informed consent document taking place in lieu of an informed consent discussion between physician and patient. Up to 75% of written consent forms are incomplete, (Shojania, 2001) and only 26% of surgical consent forms addressed the four key elements of informed consent (benefits, risks, alternatives, and educational information) (Bottrell, 2000). Adding to the problem of incomplete consent is a lack of "informed" consent: patients and their families do not easily understand most current informed consent documents (Denham, 2008).

Discordant expectations about results of healthcare procedures often cause litigation. Inadequate informed consent of benefits and risks is an important underlying factor in differences in patient and physician expectations of outcomes of health care procedures and contribute to perceptions of medical malpractice (Sharpe and Faden, 1998). Although lack of informed consent is rarely the sole reason for a lawsuit, it becomes an issue when associated with an adverse outcome. Consent issues may arise for a variety of reasons, including inadequate disclosure of the benefits of the procedure, inadequate

disclosure of the risks of the procedure, failure to obtain consent for a procedure, and failure to document refusal of care when a patient refuses medical advice.

Shared decision making (SDM) is a strategy to empower the patient to actively make an evidence-based choice in his/her treatment (Charles, 1997; Charles 1999). In 2007, the state of Washington added the option of shared decision making to the statute dealing with informed consent (Kuehn, 2009, Washington State Statute, Chapter 259 SB 5930, 2007). This legislation provides that if a competent patient or representative signs an acknowledgment of shared decision making, this acknowledgment constitutes prima facie evidence that the patient gave informed consent. This requires a higher legal evidentiary standard that must be met by the plaintiff compared with the "preponderance of evidence" standard applicable to allegations of the absence of informed consent (Moulton and King, 2010). Several other states have been considering similar shared decision-making legislation (Kuehn, 2009).

Informed consent with patient "teach-back" of key information about the proposed treatments or procedures is part of the 2009 National Quality Forum's (NQF) Safe Practices for Better Healthcare (Safe Practice 5). The Consensus Panel had great concern with the frequency with which patients do not receive adequate informed consent. As communication failures between patients and healthcare providers are at the root of systems failures and human errors that lead to harm (Levinson, 1997), the NQF Consensus Panel agreed that communication is key to preventing patient harm related to lack of informed consent. Better-informed patients serve as a layer of protection against medical errors (Shojania, 2001).

We implemented shared decision making in spine surgery clinics at UW Medicine, including adopting decision aids for selected surgical procedures as well as developing anesthesia decision aids and a patient activation pamphlet. As a result of our experiences with implementation of shared decision making, we developed a physician shared decision-making training toolkit to train physicians to implement shared decision making in the clinical encounter. We measured performance of shared decision making before, during, and after implementation using various methodologies. We also measured institutional resource consumption resulting from patient complaints concerning medical care related to deficiencies of informed consent. We compared institutional resource consumption and patient safety outcomes between patient complaints and medical errors to provide perspective on the potential role of shared decision making in improving safety and liability.

Specific Aims

Hypothesis: Physician-patient miscommunication with inadequate risk communication in the informed consent process contributes to patient dissatisfaction, complaints, and medical liability associated with surgical procedures.

Methods and results will be discussed under each specific aim (SA) of the project.

SA1 Develop shared decision-making aids.

We created decision aids for anesthesia and a patient activation pamphlet to introduce the concept of shared decision making (SDM) to patients and activate them to engage in the process of shared decision making with their providers. Orthopedic surgery decision aids were chosen from commercially prepared decision aids, with particular importance of balanced and acceptable scientific evidence and videos of patient interviews.

Anesthesia Decision Aids: We developed four patient decision aids for the major types of anesthesia and postoperative pain control used in clinical practice: general anesthesia, epidural and spinal anesthesia, peripheral nerve blocks, and monitored anesthesia care (conscious sedation by an anesthesiologist). The final drafts will be field-tested at the UW Medical Center.

We followed the International Patient Decision Aid Standards (IPDAS) Collaboration criteria (Elwyn 2006) during the decision aid development process. We incorporated as many of the criteria as feasible and applicable. Some IPDAS criteria are not applicable to anesthesia, as there is not always a choice of anesthetic technique for a particular procedure, and there is usually not an alternative of "doing nothing." We included this information in the decision aids.

Each decision aid includes an introductory panel explaining that its purpose is to help the patient decide what type of anesthesia is right for them. Each decision aid includes the following elements: description of the nature of the anesthetic, the possible benefits of this technique compared to other anesthetic techniques, specific minor and major risks of this technique with evidence-based probabilities when available, a list of side effects of the technique, information about the choices available to the patient, a check for understanding, a list of references, and information about authorship and financial disclosure. Boxes with lines for writing notes and questions are provided after each major element in the decision aid. Each decision aid also includes a telephone number for patients to call to have questions answered.

For each anesthetic technique, we conducted a comprehensive literature search to identify the risks and benefits and their associated probabilities. Inclusion criteria were multi-center clinical studies conducted in 1995 or later. A literature search was conducted in mid-November 2012 to ensure that the decision aids were current at the time of this submission.

We modeled the format for the decision aids on our institutional patient education pamphlet format. There was a deliberate attempt to choose formats, fonts, and spacing to make the decision aids accessible to the patient audience. UW Medicine Patient Education Services provided language editing to ensure an appropriate reading level.

Draft decision aids were reviewed by various stakeholders for acceptance, including the American Society of Anesthesiologists Professional Liability Committee, the UW Medical Center Chief of Clinical Anesthesia, and a number of anesthesiologists practicing in the UW Medical Center Pre-Anesthesia Clinic. Based on stakeholder feedback with major concerns over the length of lists of possible risks, we modified the lists of risks to combine minor risks lacking numerical estimates of probability. We also combined related major risks such as stroke, brain damage, and death into single items to address concerns about unnecessarily scaring patients. Major and minor risks specific to each anesthetic technique with evidence-based probabilities remained on the lists.

Orthopedic Decision Aids: We gathered patient education materials from our orthopedic surgeons and attempted to develop decision aids based on the content they were already using with their patients. We drafted decision aids for total knee replacement and hip replacement. The surgical team that conducts these procedures rejected these materials, preferring to use their own materials. Evaluation of the patient educational materials that our spine surgeons were using concluded that they were not appropriate for development into decision aids. Therefore, we presented the spine surgeons with decision aids produced by various vendors. They chose the Health Dialog™ decision aids as acceptable for use in their practice due to the balanced presentation of the scientific literature and patient videos. We purchased the two decision aids that were acceptable and applicable to their practice, spinal stenosis and lumbar back pain. These decision aids consisted of booklets plus DVDs that were given to patients to read/watch after their initial clinic visit with the surgeon.

Patient Activation Pamphlet: When we discovered that surgeons did not fully understand the concept of shared decision making, we realized that patients should not be expected to understand or be ready to engage in shared decision making without some prior preparation. Therefore, we developed a patient activation pamphlet to distribute to orthopedic clinic patients so that they would be ready to engage in shared decision making when they arrived for their clinic visit.

We included in this patient pamphlet general introductory material about the concept of shared decision making using patient-friendly language. We translated basic shared decision-making elements into common language, emphasizing the concept of "sharing": share your decision process (role), share your information (context), share your questions (understanding), and share your experience (input from others). We re-emphasized these elements of shared decision making in a summary reminder list: be a team player (role), be your own expert (context), speak up (understanding), bring your support (input from others). We emphasized specific elements of shared decision making by providing room to list concerns, questions, and support group at the end of the pamphlet.

Similar to the anesthesia decision aids, we modeled the format for this pamphlet on our institutional patient education pamphlet format. We chose a three-fold letter-size format to facilitate mailing to patients prior to the clinic visit along with their appointment reminder. There was a deliberate attempt to choose formats, fonts, and spacing to make the decision aids accessible to the patient audience. UW Medicine Patient Education Services provided language editing to ensure an appropriate reading level.

This patient activation pamphlet was well received by the spine surgeons, who distributed it to their patients when they implemented shared decision making in the UW Medicine spine surgery clinics.

SA2 Evaluate patient and provider barriers to implementation of shared decision-making.

Our study identified multiple barriers to the successful adoption and implementation of shared decision making (SDM) in a surgery clinic setting. These began early in the planning phase of the project and continued on throughout the project.

Barriers to Shared Decision-Making Implementation in Clinical Setting

Our implementation occurred across two clinical settings with differing institutional structures. Early physician resistance and institutional/bureaucratic barriers created a significant delay in implementation. Following the initial constraints, busy workflow and engrained habits and patterns of practice were the primary barriers to implementation.

Physician Barriers:

- Misunderstanding about "preference-sensitive" application of SDM.
  Physicians required consistent reminder that shared decision making is applicable to preference-sensitive treatment decisions, not ALL treatment decisions. Physician definitions of "preference sensitive" often differ from the generalized definition in the literature.
- Deciding what the patient-preference sensitive treatment options are in each specific practice and planning accordingly.
  As an example, in some settings, an epidural steroid injection may be viewed as a patient-preference sensitive treatment option; in other settings, it will be viewed as a diagnostic tool. Though shared decision making ideally is applicable to diagnostic tests and tools, in practice physicians most easily understood application to treatment decisions, with application to testing implemented as a more "advanced" implementation.
- Physician "buy-in" that SDM is needed.
  Physicians were concerned about intrusion into their clinical judgment and clinical practices by the shared decision-making process and materials.
- Physicians believe they are already participating in SDM.
  Physicians don't recognize or understand the difference between shared decision making and traditional informed consent procedures.
- Resistance to additional training time needed for SDM implementation.
  Physicians did not like the idea of "training" and were resistant to taking additional time out of their busy schedule to receive additional training.

- Concerns that SDM will add time to the clinical encounter.
  Physicians already felt pressure to reduce or limit time with patients to meet scheduling demands and were concerned SDM would add time to the clinical encounter.
- Coordination of SDM.
  Physicians argue that clinical decision making occurs between multiple team members and over multiple clinical encounters.
- Providers have deeply ingrained scripts they use with patients.
  Providers have developed deeply entrenched schema that guide their interactions with patients. These are hard to revise in short training encounters.
- Scheduling training and follow-up in busy clinical settings.
  Busy clinics, combined with the "usual" unexpected disruptions, hampered scheduling of training and follow-up discussions.
- "On-the-Fly Coaching" hampered by busy practice.
  Both time and locations to do "On-the-Fly Coaching" were hard to identify and maintain in busy clinical settings.
- Provider pocket reminder cards rarely used after initial training.

Clinic/institutional Barriers:

- Displaying SDM posters in exam rooms and other common spaces in clinical setting.
  Display in common provider workspaces was achieved but display in exam rooms was not successful due to space and institutional/bureaucratic barriers.
- Multiple sites meant varying institutional policies and staff responsibilities at each location.
  Each clinic location had their own patterns of workflow, limitations of physical space, institutional barriers, and other factors that inhibited implementation. Multiple plans must be in place if working across multiple settings.
- Bureaucracy
  The need to work through multiple levels of bureaucratic "buy-in" and approval of significant time and resources.
- Turnover
  For our study the turnover, especially among trainees (e.g., medical students, residents, and fellows) created a barrier to follow staff through the entire SDM process. Plans must be made to have training follow staff as they rotate through a practice. A plan must also be in place to address ongoing new staff training.

Barriers to Decision Aid Acquisition and Distribution:

Decision aids are a key part of the shared decision-making process and are required by statute in Washington state to be part of the SDM process. Planning on how to use decision aids in an SDM program must be one of the first steps in a SDM implementation program. Decisions on what types of aid will be used, how they will be deployed, and how tracking of patient use will occur requires multiple stakeholders and can take a significant amount of time and other resources.

- Costs of producing or purchasing decision aids.
  Design and institutional (and possibly peer review) approval time are significant if internally creating decision aids. Researching and purchasing externally produced aids also takes significant resources. A decision should be made whether materials will be distributed in hard copy, via the internet, or some combination of the two.
- Disagreement over content of aids.

Some disagreement we observed included concern about overemphasis on risks "scaring" patients, questions about scientific veracity of information, and differing opinions about treatment options.

- Identifying who in the clinical setting will be responsible for distribution.
  Identifying patients by presenting condition prior to visit so they can be given appropriate decision aid can be difficult. For example, it is difficult to know which decision aid is appropriate to provide to a new patient presenting with complaint of "back pain" who may have spinal stenosis, a lumbar disc problem, or some other condition.
  Questions to address are: will the aid go out in a generic patient package, will it be sent separately, will it be given to the patient during a visit?
- Costs of distribution.
  Additional mailing or online management costs are part of distribution.
- How to ensure that patients have received and reviewed materials prior to visit.
  Patient use of aids and their health literacy should be assessed as part of SDM.
- Aids can conflict with existing patient education materials.
- How and where to make decision aids available during the visit.
  If the patient has not received an aid prior to the visit, plans should be made to have the patient review aids in the clinical setting.

Barriers to General Patient Activation:

Although decision aids are generally condition or procedure specific, we also employed a general patient activation brochure to educate patients on how to be more actively engaged in the clinical encounter with their healthcare provider. Although there are many pamphlets advising patients on preparation for their visits, they often focus on medication lists, writing down questions, and directions for parking or clinics location. Shared decision making is a new concept for patients as well as physicians. If patients are to engage in shared decision making, they need to be activated and ready for participation. Barriers include:

- Costs of designing and gaining approval of activation materials content.
- Conflict with existing patient materials about preparing for the clinic visit.
- Costs of production and distribution.
- Implementing a system of assessing whether the patient has seen/used activation material.

In addition to these barriers, patient participation may be inhibited by health literacy, language issues, cultural differences, and patient preferences for engagement in decision-making.

Summary and Conclusions

Barriers to implementation of shared decision making exist at the patient, physician, and institutional levels. Barriers include customs, culture, perceptions, health literacy, procedural concerns, and time and cost constraints. Implementation of shared decision making must address and overcome these barriers in order to achieve success.

SA3 Implement shared decision making.

We implemented shared decision making (SDM) in the elective orthopedic spine surgery practice at UW Medicine. We used the SDM Teaching Guide in face-to-face encounters to train physicians and other healthcare providers. We observed, assessed, and provided "On-The-Fly Coaching" feedback to providers during training. We also incorporated tools such as reminder cards, cue posters, decision aids, and other SDM tools into training and implementation of SDM. We developed a toolkit (*Shared Decision-making (SDM) Toolkit: Train-The-Trainer Tools for Teaching SDM in the Classroom and Clinic*) to

use in training providers to implement shared decision making into clinical encounters with patients. The toolkit has been submitted to MedEdPORTAL®.

SDM Implementation Curriculum

We developed a toolkit (*Shared Decision-making (SDM) Toolkit: Train-The-Trainer Tools for Teaching SDM in the Classroom and Clinic*) to "train the trainers" to teach physicians, other healthcare providers, and learners the definition of SDM, the rationale for its use, and how to engage patients in SDM during clinical encounters. The following is a summary of the toolkit contents and training process.

Training/Learning Objectives:

After participating in this curriculum, the provider will be able to:

- Explain the differences between informed consent and shared decisionmaking.
- Explain the ethical-legal rationales for SDM.
- Describe the key elements of Decision Aids.
- Incorporate key elements of SDM into clinical encounters with patients regarding preference-sensitive treatments and procedures.

The Provider Training Process consisted of 4 steps (Figure 1)

Step 1: Initial Provider Training
Step 2: Observation, Assessment and "On-The-Fly Coaching"
Step 3: Ongoing Assessment/Training
Step 4: Evaluation

Step 1: Initial Provider Training
This focused introductory session introduced providers to the principles and basic skills of SDM. The session was intentionally designed to be brief, lasting 20-30 minutes, depending on time constraints of participants and time allotted for discussion and questions. Trainers distributed the SDM Teaching Guide to all participants. The guide included goals and objectives of the training, a training outline, information about SDM components, and examples of SDM components from actual clinical encounters.

Content of the provider training packet included:

1. SDM Teaching Guide
2. SDM Reminder Pocket Card
3. SDM Cue Poster
4. Patient Activation Brochure
5. SDM Assessment/Observation Checklist
6. SDM Implementation Barriers and Troubleshooting
7. SDM Resources
8. Implementation Evaluation Survey

Trainer provided brief introductory remarks about the following:

1. Differences between informed consent and SDM.
2. Ethical/legal rationales for SDM.
3. Key elements of SDM (including teach back) and how to incorporate them into the clinical encounter.
4. Commonly missed elements of SDM in clinical encounters.
5. Memory aids. Distributed "SDM Reminder Pocket Cards" and "SDM Cue Posters."
    a. SDM Reminder Pocket Cards were 3x5-inch laminated two-sided cards with the components of SDM on both sides. They were meant to be easily carried by a provider or staff, such as in a pocket, on a clipboard, etc., to be used as a learning tool and as a memory aid during patient/provider interactions.
    b. SDM Cue Posters were 8.5x11-inch or larger posters with the elements of SDM clearly displayed. They were intended for display in exam rooms, waiting areas, provider and staff workstations, and in any area that could prompt learning and implementation of SDM.
6. Contents and application of the patient activation brochure.
7. Contents and application of the decision aid(s).
   A critical role providers provided in SDM was the distribution of decision aids to appropriate patients. The point of diagnosis was a key time to distribute the decision aid, and the physician could discuss the role of the aid in the patient's SDM process.
8. Upcoming components of implementation including direct observation of clinical encounters which included SDM assessment and "On-The-Fly Coaching."

Providers needed to be familiar with activation brochure and decision aid contents when meeting with patients in order to answer questions and/or to offer clarification on content.

Step 2: Observation, Assessment and "On-The-Fly Coaching" of SDM in Clinical Encounters
Observation/Assessment:
In-situ observation, assessment, and coaching were key elements ensuring effective implementation of SDM in the clinic setting. By the end of Step 2, the provider was able to incorporate key elements of SDM into their clinical encounters.

Process:
Following the Initial Provider Training, the trainer and provider scheduled a series of observations and assessments of actual clinical encounters in practice settings. The number of observations and "On-the-Fly Coaching" sessions were determined collaboratively by provider and trainer.

During coaching sessions, trainers provided in-situ coaching to providers (including residents, fellows, and students) on applying what they learned during the initial training in the field. Trainers provided "real-time" feedback, and "On-The-Fly Coaching" on provider's skills in performing SDM to reinforce effective behaviors and suggest changes when necessary.

The SDM checklist helped the trainer provide "real-time" feedback and facilitate "On-The-Fly Coaching" to the provider. The checklist also made explicit to providers and other learners the essential skills associated with SDM.

Steps for using the assessment tool:

- Trainer observed the actual clinical encounter in the practice setting and used an SDM checklist to assess whether the provider and patient were engaging in all elements of SDM.
- Provider completed a SDM checklist at the completion of each clinical encounter to self-assess their perception of whether each SDM element was implemented in the clinical encounter.
- Trainer and provider compared checklists. If there was a discrepancy in provider and observer assessments, they discussed how and why each person scored the assessments the way they did.
- Identified barriers and offered real-time feedback and coaching.

Steps for "On-the-Fly Coaching":

- Trainer and provider discussed and approved an area/time in the practice setting where and when brief "On-The-Fly Coaching" could occur. This could be after every observed patient encounter, at designated training times such as lunch or break, or before/after the workday.
    - The choice of when to provide feedback influenced the choice of location. Immediate feedback was often given in a hallway between patient encounters or in a workspace. Reviews of multiple encounters during breaks/lunch or before/after the workday was done in a workspace, office, meeting room or break area.
- Trainer reviewed assessment(s) for designated observation period and reviewed patterns of incorporation of SDM into clinical encounters.
    - "On-The-Fly Coaching" needs were based on assessments of direct observations.
- Trainer then provided real-time "On-The-Fly Coaching" on needs identified from assessments.
    - Use of SDM Teaching Guide, memory aids, best practice examples, role playing, and other techniques were used to immediately offer the provider SDM methods to learn and apply in future clinical encounters.
    - The goal was for the provider to be able to incorporate all elements of SDM in the clinical encounter with a patient.

Step 3: Ongoing Assessment/Training
A system of ongoing assessment needs to be established to assess "stickiness" of learning and progress of provider "uptake" over time. Changing deeply ingrained patterns of communication takes time, training, and ongoing institutional support. Tools such as, but not limited to, ongoing provider assessments, quizzes or exams, and surveys can be used to assess SDM learning and application, and additional training can be applied based on observed needs.

A protocol must be established for when the initial training is complete. This might be an assessment of provider skills and improvement, a set time training process based on organizational resource constraints, or any other method that allows for a clear decision on the scope of initial training.

Ongoing Training:
SDM training should be viewed as an ongoing process, not a single time point of engagement. Organizations seeking to implement SDM as routine practice need to commit time and resources, including curricular time for ongoing support of clinician training. Our toolkit provided a comprehensive list of resources for this purpose.

- Ongoing support/refresher training for providers and core staff
    - Periodic refresher training should be used as an ongoing training tool.
    - These could be in-person trainings or could be online trainings facilitated by an outside resource.
- New staff
    - SDM training should be a codified part of new staff orientation and training.
- Medical student, resident and fellow turnover
    - If medical students, residents, and fellows are part of the practice environment, a program must be developed to address ongoing training needs.

By the end of Step 3, the provider(s) will be able to consistently identify missing elements of SDM and incorporate the key elements of SDM into clinical encounters.

Step 4: Evaluation
A verbal process evaluation must be conducted at a designated time(s) in the SDM training and implementation process. This survey should address:

- Do you feel competent in your ability to implement SDM in clinical encounters?
- Training successes? “What Worked?”
- Training shortcomings?
- Barriers to implementation?
- Ongoing/future training needs?
- What to do differently?

Additional SDM Implementation Issues and Concerns:
There are a number of other tasks in addition to training that will enhance the success of implementation. These planning and systems engagement issues include, but are not limited to:

1. Decision aids:
    a. Decision aids must be approved/peer reviewed. Decide whether to develop these aids internally and submit for review process or to acquire existing aids.
    b. A critical role providers can provide in SDM is the distribution of decision aids to appropriate patients. The point of diagnosis is a key time to distribute the decision aid, and the provider can discuss the role of the aid in the patient’s SDM process.
2. Patient Activation.
    SDM is an interactive process between the provider(s) and the patient. Patients may not expect or understand the SDM process. Activate the patient to take a more active role in the decision-making process related to preference-sensitive treatment options by distributing a patient activation tool as well as establishing the patient role at the beginning of each clinical

encounter. Some providers are "prescribing" patient activation materials as part of their clinical practice.

3. Define SDM preference-sensitive conditions and treatments in your practice setting.
   Example: In some clinical settings, an epidural steroid injection is understood to be a SDM preference-sensitive treatment option, whereas in other clinical settings, it is understood as a non-SDM preference-sensitive diagnostic tool.
4. Identify your trainer/training team.
   a. Designated trainer(s) must become conversant in theories and concepts of SDM.
   b. Trainer must be familiar with all SDM decision aid content.
5. Engage support staff such as nursing, medical assistants, patient care coordinators, therapists, and/or any other members of the direct care team.
   Any staff personnel who work directly with patients should be familiar with the basic concepts of SDM and be comfortable with the content of any SDM-related materials given to the patient so that they can actively engage with the patient to answer questions and to assist in the SDM process.
6. Engaging administration, such as clinic manager and support staff supervisors.
   Administration will aid in facilitating such tasks as distributing decision aids and placing SDM reminder/cue materials such as posters as well as in managing new workflow patterns associated with implementing SDM.
7. See list of potential barriers/issues/concerns and troubleshooting tips.
8. Review background materials and additional training and implementation resources.

Summary and Conclusions

Implementation of shared decision making during clinical encounters with patients requires clinician understanding of the principles and basic skills of shared decision making. Success can be promoted through patient activation combined with brief provider training plus in situ observation, assessment, and coaching.

SA4 Compare quantity, quality, and costs of patient complaints and risk management transactions in patients at the University of Washington Medical Center.

Purpose:

We analyzed hospital risk management files from a 1-year period to assess the role of the elements of informed consent and shared decision making (SDM) in patient complaints related to medical care. The goal of this study was to measure institutional resource consumption allocated to these types of patient complaints. We compared this to institutional resources applied to address medical errors reported by healthcare providers to provide a benchmark for resource comparison. We hypothesized that patient complaints involving elements of shared decision making represent an important resource savings equivalent to preventing medical errors in hospital patients.

Methods:

Inclusion criteria were risk management files that were open between January 1, 2010, and December 31, 2010, and involved patient care. Risk management files that did not involve patient care (e.g., visitor falls) were not included (number unknown). Exclusion criteria were internal quality reviews that lacked any patient complaint or disclosure of quality concerns to individual patients (n=65) and files with inadequate information for analysis (n=4). Minor patient complaints that were resolved by the patient relations staff without creation of a risk management file were not included.

For each file included in the analysis, the following data were abstracted: medical service and procedure associated with the complaint or error, harm score, patient age, gender, compensation

(write-off of bills, reimbursement for care expenses, settlement or other payments to the patient), and whether a lawsuit was filed. The following outcomes were assessed as present or absent in each case: change in the planned procedure, extra tests or treatment increased level of care (longer hospitalization, increased level of care in hospital, additional outpatient treatment, unplanned admission or readmission, or emergency room visit), or new physical injury.

Definition of variables and measurement: Any file in which a patient complained directly (verbally or in writing) or indirectly (through their healthcare provider) to the Risk Management office was classified as a complaint. Any file reflecting a formal claim or lawsuit was also classified as a complaint. All other files were classified as medical errors.

The nature of the complaint or medical error was classified into categories that reflect specific elements of informed consent and shared decision making as well as common types of medical errors. Each case could be classified into multiple categories.

Resources used during resolution of complaints and errors were measured by document complexity and length plus document counts and staff involvement. Documents included file notes, letters, emails, telephone notes, review documents, and grievance committee reports. The staff or physician time involved in producing each document was estimated based on the experience of Risk Management staff. The following estimates were used to convert document count and complexity to staff and physician hours (assignment indicated in parentheses):

- Enhanced notes (staff): 15 minutes per short note, 30 minutes per intermediate note, 1 hour per extensive note.
- Response letter to patient (staff): 30 minutes per short letter, 1 hour per long letter, 2 hours per very long and complex letter.
- Clinical review (physicians): 1 hour per short email, 2 hours per lengthy email and/or telephone note, 4 hours per substantive review with written review document.

Costs were estimated at $50 per hour for risk management staff and $300 per hour for physician time.

Statistical Analysis: Patient and case characteristics were compared by t-test for continuous variables and chi-square or Fisher's exact test for categorical variables. Resource use in hours and estimated dollar costs were compared between complaints and errors by Student's t-test. Harm scores were compared by Mann Whitney U test. Two tailed tests were used with $p<0.05$ considered statistically significant.

Results:

The 198 risk management files open during the study year included 82 patient complaints (41% of total risk management files) and 47 medical errors (24% of total risk management files). These 129 cases met inclusion criteria and were included in the analysis. There was no difference in age (mean 50 years) or sex (51% women) between patients filing complaints and patients involved in medical errors (Table 1). Surgery was the most common source of both patient complaints and medical errors, with no statistically significant difference in proportion of complaints versus errors between general service areas (surgery, medicine, procedures, anesthesia, Table 1).

Table 1: Patient and Case Characteristics in Complaints vs. Medical Errors

	Total N=129	Complaints N=82	Medical Errors N=47	p value
Age in years				0.247
Mean (Standard Deviation)	50 (19)	52 (17)	47 (23)	
Interquartile Range	34-62	40-62	29-65	
Sex (n=127)				0.422
Female	65 (51%)	43 (52%)	22 (49%)	
Service				0.124
Surgery	47 (36%)	30 (37%)	17 (36%)	
Medicine	35 (27%)	21 (26%)	14 (30%)	
Procedures	27 (21%)	14 (17%)	13 (28%)	
Anesthesia	20 (16%)	17 (21%)	3 (6%)	

N=129 unless otherwise noted (missing data excluded). P values for differences between complaints and medical errors were calculated by t-test (age), Fisher's exact test (sex), and chi-square test (service).

In contrast to errors, complaint files tended to cite multiple complaints related to a single episode of care. There were 117 complaints contained in the 82 complaint files (1.4 complaints per file) compared to 49 errors in the 47 medical error files (1.0 errors per file). The nature of most complaints was treatment risks (52%), medical errors (22%), treatment alternatives (20%), risks or seriousness of the condition being treated (16%), and the nature of treatment (12%). Other less frequently occurring complaints involved uncertainties associated with treatment (9%), the nature of recovery (7%), and anticipated benefits of treatment (5%, Table 2). In contrast, the nature of most errors was equipment injuries (23%), diagnostic delays or failures (19%), medication errors (15%), and laboratory errors (11%). Other errors occurring in 5% or more cases were medical or surgical management errors (9%), wrong treatment (9%), retained foreign bodies (9%), and risks of the treatment (6%, Table 2).

Table 2: The Nature of Complaints and Errors

Nature of Complaints (n=82 files)	**n (%)**
Risks of treatment	43 (52%)
Medical error	18 (22%)
Alternatives to the treatment	16 (20%)
Risks or seriousness of the condition being treated	13 (16%)
Nature of the treatment	10 (12%)
Uncertainties associated with the treatment	7 (9%)
Recovery (nature, duration, or discomfort)	6 (7%)
Benefits of treatment	4 (5%)
Total Complaints	*117 (140%)*
Nature of Errors (n=47 files)	n (%)
Equipment injury	11 (23%)
Diagnosis delay or failure to diagnose	9 (19%)
Medication error	7 (15%)
Laboratory error	5 (11%)
Retained foreign body	4 (9%)
Wrong treatment	4 (9%)
Medical or surgical mismanagement	4 (9%)
Risks of treatment	3 (6%)
Nature of treatment	1 (2%)
Patient fall	1 (2%)
Total Errors	*49 (104%)*

Percentages based on the number of complaint (n=82) or error (n=47) files. Percentages sum to >100% due to multiple complaints or errors per file. Percentages sum to greater than 140% or 104% due to rounding. Medical errors leading to complaints included medication errors (n=5), equipment injuries (n=3), diagnosis errors (failure or delay, n=3), retained foreign body (n=2), wrong treatment (n=1), patient fall (n=1), nursing error (n=1), and miscellaneous (n=2).

Complaints involved significantly more staff and physician time for resolution compared to errors ($p<0.01$), whereas errors were more likely to result in compensation (and higher compensation) in the form of write-off or reimbursement treatment ($p<0.01$, Table 3). Mean staff time per complaint file (10.7 hours) was double that for error files (5.8 hours, $p<0.01$). Similarly, mean physician time per complaint file (5.5 hours) was significantly higher than mean physician time per error file (3.3 hours, $p<0.01$). In contrast, most error files (62%) involved some compensation for treatment compared to the minority (24%) of complaint files ($p<0.01$). The size of compensation was higher in error files (mean $4,302) compared to complaints (mean $702, $p<0.01$, Table 3).

Table 3: Resource Expenditures for Complaints and Medical Errors

	Total N=129	Complaints N=82	Medical Errors N=47	p value
Staff hours: Total	1140	866	274	
Mean per file	8.9	10.7	5.8	
(SD)	(7.5)	(8.1)	(5.2)	<0.01
Physician hours: Total	600	443	157	
Mean per file	4.7	5.5	3.3	
(SD)	(5.0)	(5.3)	(4.2)	<0.01
Staff salaries($): Total	$57,012	$43,313	$13,700	
Mean per file	$442	$528	$291	
(SD)	(375)	(404)	(258)	<0.01
Physician salaries ($): Total	$180,000	$132,900	$47,100	
Mean per file	$1,395	$1,621	$1,002	
(SD)	(1,505)	(1,590)	(1,264)	0.01
Staff + MD total salaries ($): Total	$237,013	$176,213	$60,800	
Mean per file	$1,837	$2,149	$1,294	
(SD)	(1,742)	(1,867)	(1,351)	<0.01
Write off or reimbursed expense	49 (38%)	20 (24%)	29 (62%)	<0.01
Total	$259,796	$57,598	$202,198	
Mean per file	$2,014	$702	$4,302	
(SD)	(8,865)	(3,945)	(13,524)	<0.01
TOTAL COSTS	$496,808	$233,810	$262,998	
Mean per file	$3,851	$2,851	$5,596	
(SD)	(8,940)	(4,455)	(13,512)	.376

SD=standard deviation
P values for differences between complaints and errors determined by Fisher's exact test for proportions and Mann Whitney U test (with exact p-values) for hours and dollar amounts

Patient complaints were more likely than errors to result in some new physical injury to the patient (n=57, 70% vs. n=8, 17%, p<0.01). However, when measured by harm score, patient harm in complaints was similar to patient harm in medical errors. The mean harm score for each group was 4 (standard deviation 2, p=0.377). Both groups of files had similar percentages of harm scores in the range of 6-9 (n=8, 10% of complaints vs. n=6, 13% of errors). All complaints and errors resulted in some treatment or increased level of care, either within the hospital or clinic or elsewhere. Patient complaints were more likely than errors to result in an emergency room visit (n=13, 16% vs. n=1, 2%, p=0.017).

The results of this analysis are under preparation for submission to a health policy journal. Submission is planned for December 2012.

Summary and Conclusions

Patient complaints reveal significant potential for improvement of patient safety. Complaints related to elements of informed consent were more likely than medical errors to result in new physical injury and emergency department visits. Patient complaints involving the elements of shared decision making represent significant potential cost savings, equivalent to preventing medical errors in hospital patients.

SA5 Evaluate patient satisfaction and provider informed consent process before and after implementation of shared decision making.

This aim was addressed using two methodologies:

1. anonymous survey of clinic patients
2. audio recordings of clinical encounters supplemented with a patient survey

Methods:

Anonymous patient survey in clinics: We conducted a survey of clinic patients to obtain patient assessments of provider performance of specific elements of informed consent and shared decision making during their clinic visit. Eligibility criteria were patients visiting for a new problem or a preoperative visit. We collected information on performance of the following elements of consent and shared decision making: nature of the condition or procedure, alternatives or choices for treatment, risks and benefits, and preferences. Specifically, we asked patients if the doctor explained their condition (nature), discussed different treatment options (alternatives), explained pros and cons of their choices, asked which treatment choice the patient thought best (preferences), and understood their concerns. For each item, we included a follow-up question: Did he/she use words you could understand? This addressed an element of shared decision making that promotes communication in patient-friendly language to promote understanding. We also elicited general satisfaction with the clinic visit and provided an opportunity for open-ended responses. This survey was conducted in the orthopedic, general surgery, and pre-anesthesia clinics. All surveys included demographic information such as age, sex, education, and overall health status that have been found to be correlated with patient satisfaction. The survey also elicited information about how patients prepared for their visit (eliciting input from trusted others, internet search, written resources, and writing down questions to ask).

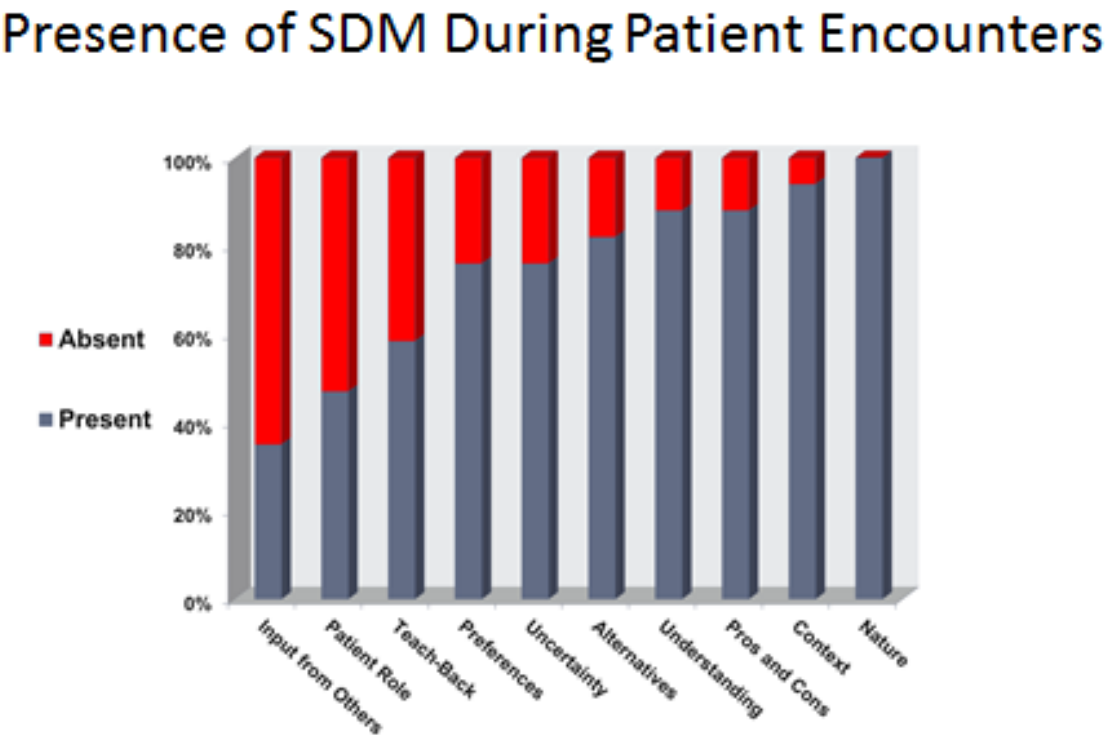
Audio recordings: We audio recorded clinic encounters between spine surgery clinic providers and patients before and after implementation of shared decision making in the spine surgery clinics. All patients and providers subject to these procedures provided informed consent. Eligibility criteria were new patients or preoperative visits. Visits in which treatment options were not discussed (e.g., referral to a different specialist, diagnostic discussion with orders for further testing to determine the nature of the condition) were excluded. At the conclusion of each visit, the patient completed a survey similar to the anonymous clinic survey, providing their assessment of the same elements of informed consent (nature, alternatives, risks and benefits, and concerns). All audio tapes were transcribed for scoring.

The scoring of audio recordings is still in progress. Several audio transcripts will be scored by two investigators/staff to ascertain reliability. If reliability was < 0.75, then all transcripts will be scored by two raters and consensus used to establish a reliable final score. Scoring will be conducted using the IDM-18 scoring system of Braddock 2008, giving 1-2 points for each of the nine elements of shared decision making evident in the recording. One point is given if the element is included by either provider or patient. Two points are given if both provider and patient participate in some verbal interaction about that element. In addition, a tenth element of "teach back" will be scored to address the specific requirements in Washington state for shared decision making (Washington State Statute). Scores from the pre-implementation phase will be compared to post-implementation to assess whether providers improved their performance of shared decision making after the training (see Specific Aim 3 describing training for implementation). The teach-back element will not be included in this before-after comparison so as to avoid inflating post-implementation scores.

To address concerns that the formal scoring may differ from patient assessments of shared decision making during the clinic visit, we will also compare patient survey responses to scores from the audio tapes to assess whether scoring matches patient assessments of the specific elements included in the

survey. The survey from patients participating in the audio taped encounters will also be compared during the two time periods (before and after SDM implementation).

Results:
We audio taped 46 clinical encounters prior to implementation of SDM in the spine clinic and 33 encounters after implementation. Provider subjects included four attending surgeons, three physician assistants, and two orthopedic spine surgery fellows. Audio recording results are not yet available. Preliminary results based on observation and assessment during the implementation of SDM in the spine clinics suggests that the most challenging elements of SDM were establishing the patient role in decision making, encouraging patients to seek input on their decisions from trusted others, eliciting patient preferences for treatment choices, and incorporating teach-back to assess patient understanding of the clinical issues involved in their treatment options (Figure 2). We expect improvement in those elements between the pre-implementation and post-implementation phase of the study. We hypothesize moderate improvement in overall scores, with most improvement centered on better performance of these specific elements in the post-implementation period.



Results from the anonymous clinic survey revealed that patients visiting an orthopedic clinic reported that surgeons usually explained the nature of their condition (93%) and most patients were told that there was >1 treatment choice (77%). These results are consistent with the observational results reported above. However, 20% of patients reported that they weren't presented with the pros and cons of their choices and 25% were not asked which choice they preferred. Analysis of patient surveys from subjects participating in audio recorded clinical encounters has not yet been completed. Based on the anonymous survey results, we expect improvement in elicitation of patient preferences in the post-implementation compared to the pre-implementation phase of the study.

Summary and Conclusions

Physicians find it challenging to establish the patient's role in shared decision making during clinical encounters, to encourage patients to seek input when making decisions, and to elicit patient preferences for treatment choices. Patients agree, reporting that they are rarely asked their preference among treatment alternatives. There is potential for improvement in provider performance of shared decision making through training, practice, and ongoing coaching.

List of Publications and Products

Mincer SL, Adeogba S, Bransford RJ, Chandanabhumma P, Lam MS, Lee MJ, Posner KL, Robins LS, Domino KD. Shared Decision-making (SDM) Toolkit: Train-The-Trainer Tools for Teaching SDM in the Classroom and Clinic. MedEdPORTAL® (in submission).

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