

Background

Definition

Shared decision making is a key component of patient-centered care, *“a process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences.”*¹ Shared decision making is appropriate for preference-sensitive conditions in which there is high-quality clinical evidence for more than one treatment or management option or screening **or where there is lack of evidence and no clinical consensus on the best option**. Shared decision making is not appropriate when clinical evidence highly favors one process or treatment such as for immunization against measles, mumps, rubella (MMR) or against antibiotics for a common cold,² see **Figure X**, below.

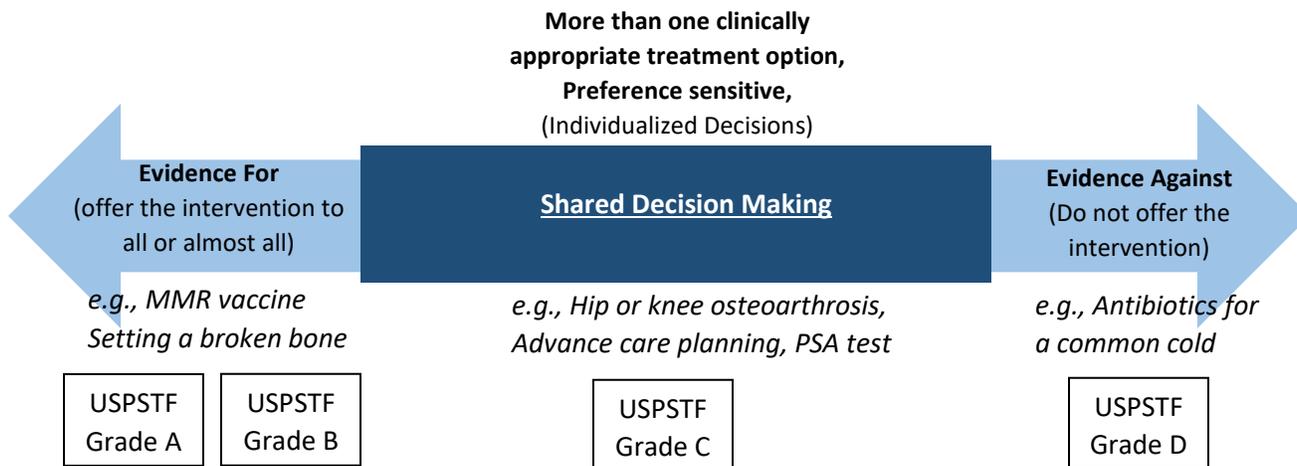
Further, shared decision making aligns with the United States Preventive Services Task Force designations in services or screenings with A and B grades are recommended or *“have high certainty the net benefit is substantial”* (A) or *“high certainty the net benefit is moderate or moderate certainty that the net benefit is moderate to substantial”* (B), D grade indicates a recommendation against the service *“moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits,”* and a C grade indicates a potential good fit for shared decision making in which *“selectively offering or providing this service to individual patients [is] based on professional judgement and patient preferences [with] moderate certainty that the net benefit is small.”*³ **As with all clinical choices, doing nothing is an option**. In all clinical interactions good communication is a key component of high-quality care. At an organization level, a patient decision aid is necessary for reliability **of delivering high-quality shared decision making**.

This process is different from informed consent and education only and also distinct from motivational interviewing. **In both shared decision-making and informed consent, the patient receives information about treatment or screening and makes the decision**. Informed consent, however, is often practiced today through the *“ritualistic recitation of risks and benefits,”* enumerated on a written form with little or no engagement of the patient and little or no evaluation of whether the patient understands risks or benefits.

The essential components of a shared decision making process are the clinician’s knowledge and perspective, the patient’s informed preferences, and a decision aid that helps provide objective information about available treatment options and engages the patient by making clear that there is a decision to be made and that the person undergoing the treatment can choose to be the locus of decision making. The decision aid presents the risks and benefits of each treatment option in a way that is designed to help patients understand the likelihood of benefits or harms occurring and help them consider what benefits and/or risks matter most to them. Shared decision making allows for

communication between a provider and patient, and in some cases family members or others, about risks, benefits, and exploration of values and goals.

Figure X: Appropriateness of Shared Decision Making⁴



Benefits

Shared decision making for preference-sensitive conditions has been shown to help people gain knowledge about their health condition(s) and possible outcomes of care and to have more confidence in their decisions.⁵ The process has also been associated with improved patient satisfaction with care, improved health outcomes, and with better appropriateness of care.^{6,7} Knee and hip replacement and prostate cancer screening are the most well-studied health conditions for use of shared decision making and have seen broader adoption of the process and of patient decision aids. Shared decision making can also help to reduce health disparities such as increasing rates of total knee replacement for black patients with osteoarthritis of the knee to rates closer to that of white patients.⁸

Current Practice

Unfortunately, involving patients as equal partners in health care decisions that have multiple clinically appropriate options by fully discussing risks and benefits remains limited within clinical practice. Barriers to implementing shared decision making into clinical practice include lack of enough provider time, providers being overworked, lack of training, lack of structural support including through electronic health records and clinic general workflow, fear of revenue loss, and decision aids themselves not being applicable to the specific patient’s characteristics or not being applicable to the specific clinical situation.^{9,10} Having a supportive clinical culture is paramount to successful implementation starting with engaged leadership.¹¹ Other than the converse of the barriers listed above, facilitators include providers being motivated and seeing a positive impact on the clinical process or on a patient’s outcomes.⁷

Shared decision making is identified in the statute that formed the Bree Collaborative as a mechanism to increase use of evidence-based best practice.¹² Shared decision-making or use of patient decision aids have been a component in the majority of Bree Collaborative recommendations and is aligned with the organizations goals of better health care quality, outcomes, and affordability.

Recommendations

The Shared Decision Making workgroup's goal is state-wide movement toward greater use of shared decision making in clinical practice at a care delivery site and organizational level. The goal is for all care delivery sites to move toward greater adoption using a stages of change framework (i.e., precontemplation, contemplation, preparation, action, maintenance). In some locations will be starting in the precontemplations (e.g., leadership engagement and buy-in) while others will be ready to start action (e.g., pilots or implementation of shared decision making in one health service area such as abnormal uterine bleeding), and others will be maintaining or spreading use.

The workgroup frames the recommendations under four priority focus areas:

- A common understanding and shared definition of shared decision making and the benefit of shared decision making, as defined above
- Ten priority areas as first steps for the health care community
- Best practice implementation framework while accepting others
- Documentation, coding, and reimbursement structure to support broad use

The process of implementation and the specific clinical areas to be implemented are expected to be different from location to location as some areas have already seen greater uptake of shared decision making. Best practice is to link adoption of shared decision making to ongoing work within the organization to advance goals on which the organization is already working.

The workgroup prioritized ten health conditions for which shared decision-making is appropriate, staged the ten areas based on prevalence of use, availability, and HCA certification (i.e., existing pilots to widely used; certified, not widely used; aids available, not certified, not widely used; no aids available or few aids), and categorized by type of health care service (i.e., procedural/surgical, advance care planning, screening, behavioral health). Similar areas, such as those that concern surgical procedures or those that concern whether or not to undergo screening for a type of cancer, are assumed to assist with implementation of one another based on similar workflows. For example, learnings from a pilot for breast cancer screening could be applied to prostate cancer screening as the same type of providers may be involved and the patient decision aid may be implemented at the same place within the care stream (e.g., prior to a family medicine visit).

See **Appendix X** for a detailed list on these ten areas, the aids that have been currently certified by the HCA, and suggestions for placement within the care stream.

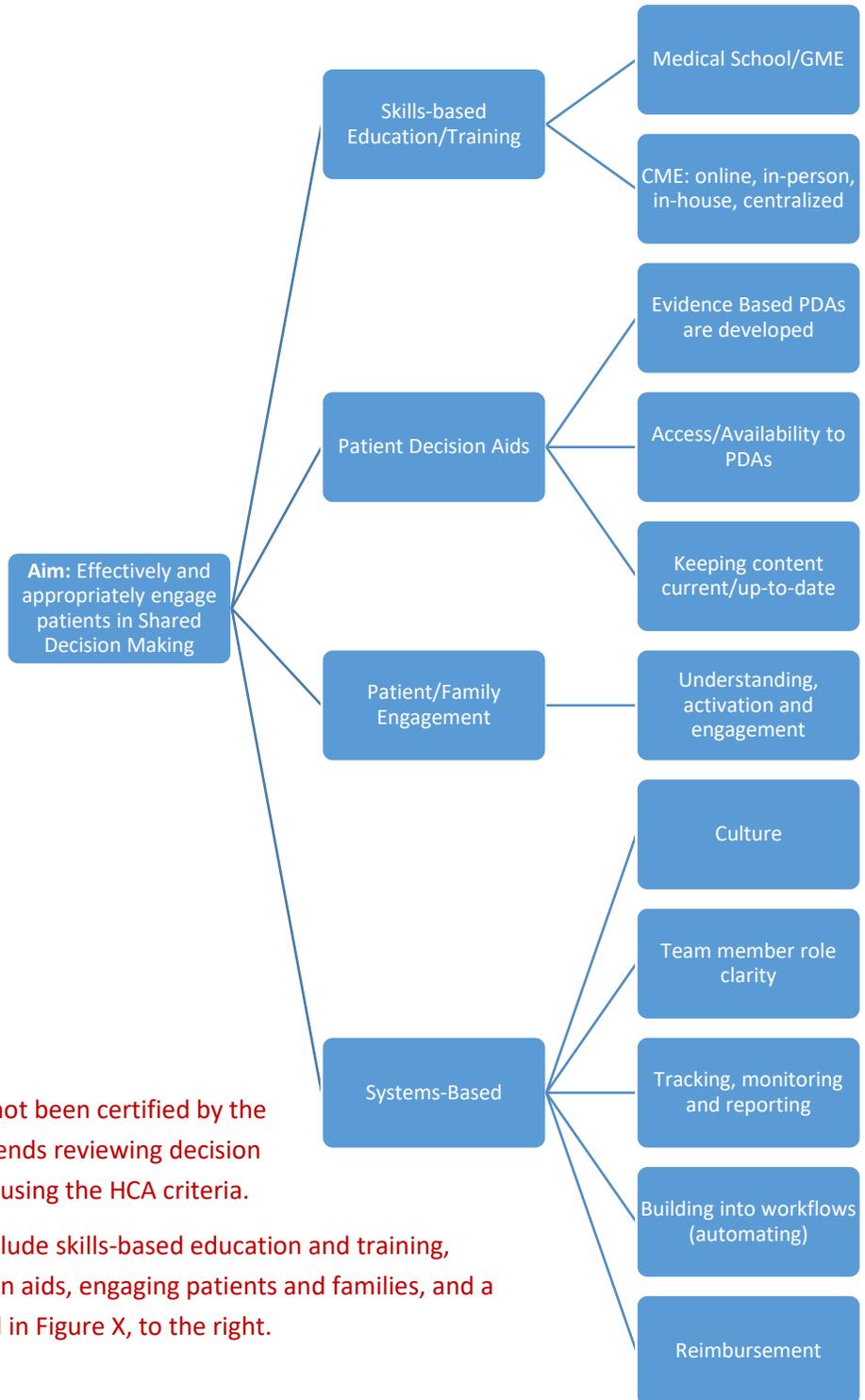
- Abnormal Uterine Bleeding (Stage III, procedural)
- Advanced Care Planning (Stage I, advance care planning)
- Attention Deficit Hyperactivity Disorder Treatment (Stage III, behavioral health)
- Breast Cancer Screening (Stage III, screening)
- Depression Treatment (Stage III, behavioral health)
- Knee and Hip Osteoarthritis (Stage I, procedural)
- Opioid Use Disorder Treatment (Stage IV, behavioral health)
- Prostate Specific Antigen Testing (Stage III, screening)

- Spine Surgery (Lumbar Fusion) (Stage I, procedural)
- Trial of Labor After Cesarean Section (Stage I, procedural)

The Washington State Health Care Authority (HCA) has worked to certify patient decision aids since April 2016.¹³ Washington State law allows for shared decision making **using certified patient decision aids** to meet informed consent standards and supports the shared decision making process.¹⁴ The HCA has certified patient decision aids for knee and hip osteoarthritis, advanced care planning, obstetrics (e.g., trial of labor after cesarean section, birth options for large babies), and for spine surgery.¹⁰

The workgroup does not recommend specific patient decision aids but does encourage use of HCA certified aids. HCA decision aids have been certified by the HCA medical director via adapting standards based on the International Patient Decision Aid Standards (IPDAS). More information [here](#). See the **complete HCA criteria as adapted from IPDAS in Appendix X**. If using a patient decision aid that has not been certified by the HCA, the workgroup recommends reviewing decision aids being considered for use using the HCA criteria.

Drivers of implementation include skills-based education and training, accessibility of patient decision aids, engaging patients and families, and a supportive system as outlined in Figure X, to the right.



Recommendations for Stakeholder Actions and Quality Improvement Strategies

These recommendations are not intended to be used in lieu of medical advice.

Patients and Family Members

- Think about the type of role that you want to have in making your medical decisions with your providers and clinical team. Shared decision making is a good fit for types of treatments or screening that are preference-sensitive and take into account the importance of your opinion of what happens to you and where the evidence is either not strongly supportive or against the treatment or screening or where there is no clinical evidence or no clinical consensus about what to do.
- Review the background listed in the report and figure X on page X to see where shared decision making should be used.
- If you are receiving or thinking about receiving one of the ten procedures or screenings listed on page X, ask your provider if they can have a shared decision making conversation with you. Ask whether a patient decision aid is available.
- Make sure that you understand the risks and benefits of any procedure or screening. Ask your provider or other members of the clinical team to answer your questions.

Health Care Delivery Organizations and Systems

Stage of Change	Steps
Precontemplation	<ul style="list-style-type: none"> • Review your organization’s mission, vision and values. • Define how shared decision making can help support your organizational goals and align with regional, state-wide, and Federal programs and expectations.
Contemplation	<ul style="list-style-type: none"> • Define a framework with which to implement shared decision making. If using the NQF Playbook, review the basic implementation examples for all 6 fundamentals. Implement the components of examples within basic Leadership and Culture implementation (page 6). • Identify clinical champions who will be willing to help educate their peers. • Select an appropriate training for your providers and staff about shared decision making. See list of training programs in Appendix X.
Preparation	<ul style="list-style-type: none"> • Spread awareness about shared decision making broadly within your organization. Use the definitions and materials within this report. <ul style="list-style-type: none"> ○ <i>Review the Playbook’s basic to advanced Healthcare Team Knowledge and Training examples (page 12) and implement components of basic Knowledge and Training.</i> • Work with your clinical champion(s) to educate providers about the value of shared decision making and how to have a good conversation that uses the patient decision aid or references the patient decision aid if the aid will be distributed to patients prior to the visit. • Select one of the ten clinical areas to pilot (e.g., breast cancer screening). • Select a patient decision aid or aids to integrate into the care stream. If using a patient decision aid that has not been certified by the HCA, the workgroup recommends using the IPDAS-based criteria adapted by the HCA within Appendix X.

	<ul style="list-style-type: none"> • Define where in the care stream to use the aid (e.g., prior to visit via email). • Clearly identify roles for care team members. Non-clinical staff can have a shared decision making conversation and/or patients can be send the patient decision aid prior to the visit. • Assist clinicians by providing templates for documentation of use of shared decision-making. • Conduct clinic- or system-wide training. • Performance metrics (TBD)
Action	<ul style="list-style-type: none"> • Implement your shared decision making pilot. <ul style="list-style-type: none"> ○ <i>Review the Playbook’s Fundamental 4: Action and Implementation (page 15) and implement the components under basic.</i>
Maintenance	<ul style="list-style-type: none"> • Evaluate use of the shared decision making process including feedback on the specific patient decision aid. <ul style="list-style-type: none"> ○ <i>Review the Playbook’s basic to advanced Tracking, Monitoring, and Reporting examples (page 18) and implement components under basic.</i> • Decide whether to change any components within the pilot of not working. • Spread to another clinical area.

Providers

- Think about how you engage with your patients in the ten areas listed on page X, if applicable to your practice.
- Participate in skills training
- Actively recommend and use high quality decision aids with your patients.
- Document use of SDM in the medical record

Provider Associations

- TBD

Patient Advocates and Organizations

- TBD

Health Plans and Professional Liability Carriers

- Reimburse for and/or incentivize use of shared decision aids for the 10 topic areas in FFS
- Incorporate shared decision making requirements as standards for value-based models (e.g., Centers of Excellence)
- Consider providing a range of high quality decision aids to providers and patients.
- Consider supporting continuing education for clinicians
- Consider providing discounts for professional liability coverage for providers engaging in SDM.

Employers

- Incorporate shared decision making requirements as standards for value-based contracting (e.g., Centers of Excellence)
- Others?

Washington State Health Care Authority

- Encourage patient decision aid developer community to develop patient decision aids for the ten priority areas.
- Certify patient decision aids for the ten areas.
- Continue to lead in promoting the spread of shared decision making using high quality decision aids.
- Include shared decision making in contracting requirements for state purchased healthcare.

Implementation Framework

There are many frameworks with which shared decision making can be implemented. All share common components and all start with health system leadership engagement. This is a necessary first step. **The workgroup recommends using an established framework for implementing shared decision making.**

The [National Quality Partner's Playbook: Shared Decision Making in Healthcare](#) is a comprehensive, pragmatic framework. The Playbook organizes the process into implementation fundamentals, each which include basic, intermediate, and advanced steps for health care organizations. The eight fundamentals include:

- Leadership and culture
- Patient education and engagement
- Healthcare team knowledge and training
- Action and implementation
- Tracking, monitoring and reporting
- Accountability

Alternatively, the Agency for Healthcare Research and Policy (AHRQ) developed the SHARE (Seek, Help, Assess, Reach, and Evaluate) approach outlining implementing shared decision making into clinical process.¹⁵ At an individual level, SHARE organizes shared decision making into seeking patient participation, helping the patient explore and compare treatment options, assessing patient values and preferences reaching a decision with the patient, and evaluating the patient's decision. At a health care organization level, steps to implementation within SHARE include:

1. Get leadership buy-in.
2. Develop an implementation team.
3. Select an approach that is tailored to your practice.
4. Provide training and ongoing support to all staff.
5. Start small, then take it to scale.
6. Create a physical setting for shared decision-making.
7. Create a library of evidence-based educational resources and decision aids.
8. Streamline shared decision-making work processes into day-to-day operations.
9. Evaluate the ongoing implementation of shared decision-making.

More information is [here](#).

Other frameworks can be used for the implementation process including:

- [Dartmouth Hitchcock](#) (i.e., Leadership, Goals and Scope of Project, Assessment, Decision Support Tools, Education and Training, Implementation, Quality Monitoring Tools)
- Those developed by individual states such as in the [Minnesota Shared Decision-Making Collaborative](#)
- [Ottawa Personal Decision Guide](#)
- American Academy of Family Physicians [A Simple Approach to Shared Decision Making in Cancer Screening](#)

What documentation is required to claim legal protection in Washington?

Washington state law outlines how providers can document SDM to achieve enhanced liability protections in the event of a claim of lack of informed consent. Essentially, providers can use an “acknowledgement of shared decision making” that outlines the communications process that was followed, including a description of the certified decision aid that was employed.

RCW 7.70.060 (2) (paraphrased)

The patient if competent or his or her representative if not competent signs an acknowledgement of shared decision making, described as follows:

- 1. A statement that the patient (or representative) and the health care provider have engaged in shared decision making as an alternative means of meeting informed consent requirements;*
- 2. A brief description of the services that the patient (representative) and provider have jointly agreed will be furnished;*
- 3. A brief description of the (certified) patient decision aid or aids that have been used;*
- 4. A statement that the patient understands the risks or seriousness of the disease or condition to be prevented or treated, the available treatment alternatives, including non-treatment, and the risks, benefits and uncertainties of the treatment alternatives including non-treatment, and*
- 5. A statement certifying that the patient (or representative) has had the opportunity to ask the provider questions and have them answered to his/her satisfaction, and indicating the patient's preference to receive the identified services.*

Documentation and Coding

In medical record - CMS – for patients with severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) \leq 35%. a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1)) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5)) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.¹⁶

G0296 Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scanning (the service is for eligibility determination and shared decision making).¹⁷

Reimbursement

Example: CMS presented a model focused on shared decision making that has since been cancelled.¹⁸ The Shared Decision Making model presented a four-step process in which 100 ACOs were randomized, 50 to the model, 50 as controls for five preference-sensitive conditions (i.e., stable ischemic heart disease, hip and knee osteoarthritis, back pain, early state prostate cancer, benign prostate hyperplasia) for a \$50 per person ACO payment for the service.¹⁹ The four steps included (1) identifying eligible beneficiaries, (2) distributing the patient decision aid, (3) shared decision making discussion, decision, and documentation, and (4) tracking and reporting. The participating ACO submits the SDM claim, operational data (e.g., total number of decision aids given, engagement rate for SDM model), and beneficiary questionnaire data (i.e., questionnaire beneficiary completes after SDM process).

Inadequate or poor communication = unhappy patients

Poor communication and lack of information are the most commonly reported sources of patient dissatisfaction in healthcare. Clinicians' perceived inability to clearly communicate with their patients, to disclose risks and benefits, and to answer their questions are common predictors of medical malpractice claims. Informed consent is often a "secondary" issue in a malpractice case that has the potential to add to liability by increasing the likelihood of a claim, the magnitude of the associated demand or the frequency of payment.

Liability claims can occur because patients and their families fail to recall what has been communicated to them. Studies also indicate that patients and physicians do not look at risk, particularly surgical risk - what matters, or is material to them - the same way, with many patients being more conservative in outlook than their physicians.

In at least 25 states (including Washington), allegations of failure to disclose are to be judged according to jury assessments of what a reasonable patient in the plaintiff's position would expect to be told prior to making a decision about treatment, rather than by professional testimony by medical experts on what physicians customarily convey. Verdicts in states that are patient oriented are significantly more frequent.²⁰ Aside from the moral and ethical imperatives, this finding adds practical weight to the importance of assuring that patients are able to understand, weigh and communicate which risks and benefits matter most to them.

Why focus on shared decision making from a liability perspective?

Litigation Prevention. An established rapport between the patient and the physician based on solid exchanges of information can prevent patient disappointment from ripening into a claim. Shared decision making encourages this type of rapport and two way flow of information, making perceived communication failures and failure to adequately surface risks that matter to patients less likely.

Shared decision making using a certified decision aid in Washington state may deter litigation for a more direct reason. While most states are yet to embed shared decision-making in legal reforms of informed consent, Washington State passed legislation in 2007 to change the informed consent law and offer clinicians who practice shared decision-making with a "certified" decision aid, a higher degree of protection against a failure to inform lawsuit.¹ The law was further amended in 2010 to enable the Washington State Healthcare Authority medical director to develop certification criteria and certify patient decision aids. As of 2019, patient decision aids have been certified for hip and knee osteoarthritis, spinal lumbar fusion, certain obstetrical decisions, topics in end of life care, and topics in

¹ There are now five states that have promoted shared decision-making in state law. Massachusetts now requires that in order to be a medical home or an accountable care organization, the state must certify the entity, and it must, in turn, encourage shared decision-making for certain preferences sensitive conditions in order to qualify.

cardiac care.²¹ More topics are in the pipeline, and are expected to be aligned with Bree recommendations.

When documented correctly in the medical record, an acknowledgement of shared decision making will help establish that the patient was provided with good information about treatment options, risks and benefits and made an informed choice based on his or her preferences. While contemplating a suit, plaintiff's counsel must also recognize and weigh the higher bar that must be overcome because of the change in evidentiary standard described more fully below.

Protection once Litigation Ensues. If an informed consent action is brought in Washington State, documented use of shared decision making using a certified patient decision aid, provides augmented protection from an adverse finding. In the case of a shared decision making meeting the requirements of RCW 7.70.060, the patient would have the burden of rebutting the physician's prima facie case by "clear and convincing" evidence rather than the "preponderance" standard that typically applies in civil litigation. The preponderance standard is "more likely than not". The clear and convincing is "substantially more likely to be true than not true, highly probable". This raises the bar significantly.

More Background - Litigating Lack of Informed Consent in more detail. The plaintiff in alleging failure to obtain informed consent has the burden of proving breach of the duty to obtain informed consent, and must make out a prima facie case of negligence. These elements may be succinctly stated as: (1) the existence of a material risk unknown to the patient; (2) the failure to disclose the risk; (3) that had the risk been disclosed, the patient would have chosen a different course; and (4) resulting injury.

The plaintiff's burden is to demonstrate these elements by a preponderance of the evidence. As to the issue of materiality, this burden has been described as follows:

- Materiality presents a jury question if any rational trier of fact could find, based on a preponderance of evidence, that a reasonably prudent person in the position of the patient, when deciding whether to submit to the proposed treatment, would have attached significance to the fact in issue. Immateriality is shown as a matter of law if no rational trier could find, based on a preponderance of evidence, that a reasonably prudent person in the position of the patient, when deciding whether to submit to the proposed treatment, would have attached significance to the fact in issue

The states are split on whether the standard is patient or provider oriented. Washington is patient oriented. In at least 25 states, allegations of failure to disclose are to be judged according to jury assessments of what a reasonable patient in the plaintiff's position would expect to be told prior to making a decision about treatment, rather than by professional testimony by medical experts on what physicians customarily convey. Verdicts in states that are patient oriented are significantly more frequent, according to at least one well done analysis.²²

Once the failure to disclose a material fact has been established (by a preponderance of the evidence), along with proximate cause, the burden of proof shifts to the physician.

The physician must provide a defense to the failure to disclose. A plaintiff's signed consent form, which sets forth the above information, constitutes prima facie evidence that the patient gave informed

consent to the treatment administered, and the patient then has the burden of rebutting this by a preponderance of the evidence.

In the case of shared decision making meeting the requirements of RCW 7.70.060, the patient would have the burden of rebutting the physician's prima facie case established by a documented acknowledgement of SDM by clear and convincing evidence rather than the "preponderance" standard that typically applies in civil litigation. The preponderance standard is "more likely than not". The clear and convincing is substantially more likely to be true than not true, highly probable.

What documentation is required to claim the protection in Washington?

Washington state law outlines how providers can document SDM to achieve enhanced liability protections in the event of a claim of lack of informed consent. Essentially, providers can use an "acknowledgement of shared decision making" that outlines the communications process that was followed, including a description of the certified decision aid that was employed.

RCW 7.70.060 (2) (paraphrased)

The patient if competent or his or her representative if not competent signs an acknowledgement of shared decision making, described as follows:

6. *A statement that the patient (or representative) and the health care provider have engaged in shared decision making as an alternative means of meeting informed consent requirements;*
7. *A brief description of the services that the patient(representative) and provider have jointly agreed will be furnished;*
8. *A brief description of the (certified) patient decision aid or aids that have been used;*
9. *A statement that the patient understands the risks or seriousness of the disease or condition to be prevented or treated, the available treatment alternatives, including non-treatment, and the risks, benefits and uncertainties of the treatment alternatives including non-treatment, and*
10. *A statement certifying that the patient (or representative) has had the opportunity to ask the provider questions and have them answered to his/her satisfaction, and indicating the patient's preference to receive the identified services.*

Additional resources:

- Shared Decision-making statute: [RCW 7.70.060](#).
- Patient Decision Aid certification regulation: [182-60 WAC](#)
- Huntington B, Kuhn N. Communication gaffes: a root cause of malpractice claims. *Proc (Bayl Univ Med Cent)* 200;16:157–61.
- Shay LA, Lafata JE. Where is the evidence? A systematic review of shared decision making and patient outcomes. *Med Decis Making*2015;35:114–31.
- Stacey D, Legare F, Col NF, et al. Decision aids to help people who are facing health treatment or screening decisions. *Cochrane Database Syst Rev*2014;(1):CD001431.
- David M. Studdert, Michelle M. Mello, Marin K. Levy, Russell L. Gruen, EdwardJ. Dunn, E. John Orav, and Troyen A. Brennan,* Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risks *Journal of Empirical Legal Studies*, Volume 4, Issue 1, 103-124, March 2007

Measurement

- **Shared Decision Making Process**

Steward: Massachusetts General Hospital

NQF #2962

- *This measure assesses the extent to which health care providers actually involve patients in a decision-making process when there is more than one reasonable option. This proposal is to focus on patients who have undergone any one of 7 common, important surgical procedures: total replacement of the knee or hip, lower back surgery for spinal stenosis of herniated disc, radical prostatectomy for prostate cancer, mastectomy for early stage breast cancer or percutaneous coronary intervention (PCI) for stable angina. Patients answer four questions (scored 0 to 4) about their interactions with providers about the decision to have the procedure, and the measure of the extent to which a provider or provider group is practicing shared decision making for a particular procedure is the average score from their responding patients who had the procedure.*

- **Informed, Patient-Centered Hip and Knee Replacement Surgery**

NQF #2958

Steward: Massachusetts General Hospital

- *The measure is derived from patient responses to the Hip or Knee Decision Quality Instruments. Participants who have a passing knowledge score (60% or higher) and a clear preference for surgery are considered to have met the criteria for an informed, patient-centered decision. The target population is adult patients who had a primary hip or knee replacement surgery for treatment of hip or knee osteoarthritis.*

- **Gains in Patient Activation Scores at 12 Months**

NQF #2483

Steward: Insignia Health

- *The Patient Activation Measure® (PAM®) is a 10 or 13 item questionnaire that assesses an individual's knowledge, skill and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale. There are 4 levels of activation, from low (1) to high (4). The measure is not disease specific, but has been successfully used with a wide variety of chronic conditions, as well as with people with no conditions. The performance score would be the change in score from the baseline measurement to follow-up measurement, or the change in activation score over time for the eligible patients associated with the accountable unit. The outcome of interest is the patient's ability to self-manage. High quality care should result in gains in ability to self-manage for most chronic disease patients. The outcome measured is a change in activation over time. The change score would indicate a change in the patient's knowledge, skills, and confidence for self-management. A positive change would mean the patient is gaining in their ability to manage their health.*

- **Back Pain: Shared Decision Making**

NQF #0310

Steward: National Committee for Quality Assurance

- *Percentage of patients at least 18 years of age and younger than 80 with back pain with whom a physician or other clinician reviewed the range of treatment options, including alternatives to surgery prior to surgery. To demonstrate shared decision making, there must be documentation in the patient record of a discussion between the physician and*

the patient that includes all of the following: Treatment choices, including alternatives to surgery; Risks and benefits; Evidence of effectiveness

- **NCQA Supplemental items for CAHPS® 4.0 Adult Questionnaire (CAHPS 4.0H)**

NQF #0007

Steward: National Committee for Quality Assurance

- *This supplemental set of items was developed jointly by NCQA and the AHRQ-sponsored CAHPS Consortium and is intended for use with the CAHPS 4.0 Health Plan survey. Some items are intended for Commercial health plan members only and are not included here. This measure provides information on the experiences of Medicaid health plan members with the organization. Results summarize member experiences through composites and question summary rates. In addition to the 4 core composites from the CAHPS 4.0 Health Plan survey and two composites for commercial populations only, the HEDIS supplemental set includes one composite score and two item-specific summary rates.: Shared Decision Making Composite, Health Promotion and Education item, Coordination of Care item*

- **CAHPS**

- Q10: In the last 6 months, did a doctor or other health provider talk with you about the pros and cons of each choice for your treatment or health care?
- Q11: In the last 6 months, when there was more than one choice for your treatment or health care, did a doctor or other health provider ask which choice you thought was best for you?

Appendix C: Guideline and Systematic Review Search Results

	Year	Title	Summary
<i>AHRQ: Research Findings and Reports</i>	2014	Decision Aids for Cancer Screening and Treatment	Cancer-related decision aids have evolved over time, and there is considerable diversity in both format and available evidence. We found strong evidence that cancer-related decision aids increase knowledge without adverse impact on decisional conflict or anxiety. We found moderate- or low-strength evidence that patients using decision aids are more likely to make informed decisions, have accurate risk perceptions, make choices that best agree with their values, and not remain undecided. This review adds to the literature that the effectiveness of cancer-related decision aids does not appear to be modified by specific attributes of decision aid delivery format, content, or other characteristics of their development and implementation. Very limited information was available on other outcomes or on the effectiveness of interventions that target providers to promote shared decision making by means of decision aids.
<i>Cochrane Collection</i>	2019	Interventions for promoting participation in shared decision-making for children and adolescents with cystic fibrosis	We were unable to identify RCTs with evidence which would support healthcare policy-making and practice related to implementation of shared decision-making for children and adolescents (aged between four and 18 years) with CF. We hope that having identified this gap in research, awareness will increase amongst researchers of the need to design high-quality shared decision-making interventions for young people with CF, perhaps adapted from existing models for adults, and to test these interventions and children's preferences in RCTs.
	2018	Interventions for increasing the use of shared decision making by healthcare professionals	We included 87 studies (45,641 patients and 3113 healthcare professionals) conducted mainly in the USA, Germany, Canada and the Netherlands. Risk of bias was high or unclear for protection against contamination, low for differences in the baseline characteristics of patients, and unclear for other domains. Forty-four studies evaluated interventions targeting patients. They included decision aids, patient activation, question prompt lists and training for patients among others and were administered alone (single intervention) or in combination (multifaceted intervention). The certainty of the evidence was very low. It is uncertain if interventions targeting patients when compared with usual care increase SDM whether measured by observation. Fifteen studies evaluated interventions targeting healthcare professionals. They included educational meetings, educational material, educational outreach visits and reminders among others. The certainty of evidence is very low. It is uncertain if these interventions when compared with usual care increase SDM whether measured by observation. Twenty-eight studies targeted both patients and healthcare professionals. The interventions used a combination of patient-mediated and healthcare professional directed interventions. Based on low certainty evidence, it is uncertain whether these interventions, when compared with usual care, increase SDM whether measured by observation.
	2017	Shared decision-making for people with asthma	Substantial differences between the four included randomized controlled trials (RCTs) indicate that we cannot provide meaningful overall conclusions. Individual studies demonstrated some benefits of SDM over control, in terms of quality of life; patient and parent satisfaction; adherence to prescribed medication; reduction in asthma-related healthcare visits; and improved asthma control. Our confidence in the findings of these individual studies ranges from moderate to very low, and it is important to note that studies did not measure or report adverse events.
	2010	Shared decision making interventions for	We included two separate German studies involving a total of 518 participants. One study was undertaken in the inpatient treatment of schizophrenia and the other in the treatment of people newly diagnosed with depression in primary care. Regarding the primary outcomes, one study reported statistically significant increases in patient satisfaction, the other study did not. There was no evidence of effect on clinical outcomes or hospital readmission rates

	people with mental health conditions	in either study. Regarding secondary outcomes, there was an indication that interventions to increase shared decision making increased doctor facilitation of patient involvement in decision making, and did not increase consultation times. Nor did the interventions increase patient compliance with treatment plans. Neither study reported any harms of the intervention. Definite conclusions cannot be drawn, however, on the basis of these two studies.
2016 (update of 2013)	Interventions for promoting participation in shared decision-making for children with cancer	No conclusions can be made on the effects of interventions to promote SDM for children with cancer aged four to 18 years. This review has highlighted the dearth of high-quality quantitative research on interventions to promote participation in SDM for children with cancer.
2015	Interventions to facilitate shared decision making to address antibiotic use for acute respiratory infections in primary care	We identified 10 published reports of nine original RCTs (one report was a long-term follow-up of the original trial) in over 1100 primary care doctors and around 492,000 patients. Interventions that aim to facilitate shared decision making reduce antibiotic prescribing in primary care in the short term. Effects on longer-term rates of prescribing are uncertain and more evidence is needed to determine how any sustained reduction in antibiotic prescribing affects hospital admission, pneumonia and death.
2013	Interventions for supporting pregnant women's decision-making about mode of birth after a caesarean	Three randomized controlled trials involving 2270 women from high-income countries were eligible for inclusion in the review. We found no difference in planned mode of birth: VBAC (risk ratio (RR) 1.03, 95% confidence interval (CI) 0.97 to 1.10; $I^2 = 0\%$) or caesarean birth (RR 0.96, 95% CI 0.84 to 1.10; $I^2 = 0\%$). The proportion of women unsure about preference did not change (RR 0.87, 95% CI 0.62 to 1.20; $I^2 = 0\%$). There was no difference in adverse outcomes reported between intervention and control groups (one trial, 1275 women/1280 babies): permanent (RR 0.66, 95% CI 0.32 to 1.36); severe (RR 1.02, 95% CI 0.77 to 1.36); unclear (0.66, 95% CI 0.27, 1.61). Decisional conflict about preferred mode of birth was lower (less uncertainty) for women with decisional support. There was also a significant increase in knowledge among women with decision support compared with those in the control group. Evidence is limited to independent and mediated decision supports.
2012	Interventions for providers to promote a patient-centered approach in clinical consultations	Forty-three randomized trials met the inclusion criteria, of which 29 are new in this update. In most of the studies, training interventions were directed at primary care physicians (general practitioners, internists, pediatricians or family doctors) or nurses practicing in community or hospital outpatient settings. Some studies trained specialists. Patients were predominantly adults with general medical problems, though two studies included children with asthma. Interventions to promote patient-centered care within clinical consultations are effective across studies in transferring patient-centered skills to providers. However the effects on patient satisfaction, health behavior and health status are mixed. There is some indication that complex interventions directed at providers and patients that include condition-specific educational materials have beneficial effects on health behavior and health status, outcomes not assessed in studies reviewed previously.
2017	Clinician-targeted interventions to influence antibiotic prescribing	We included eight reviews in this overview: five Cochrane Reviews (33 included trials) and three non-Cochrane reviews (11 included trials). We found evidence that CRP testing, shared decision making, and procalcitonin-guided management reduce antibiotic prescribing for patients with ARIs in primary care. These interventions may therefore reduce overall antibiotic consumption and consequently antibiotic resistance. There do not appear to be negative effects of these

		behavior for acute respiratory infections in primary care: an overview of systematic reviews	interventions on the outcomes of patient satisfaction and reconsultation, although there was limited measurement of these outcomes in the trials. This should be rectified in future trials. We could gather no information about the costs of management, and this along with the paucity of measurements meant that it was difficult to weigh the benefits and costs of implementing these interventions in practice.
	2016	Implementation of treatment guidelines for specialist mental health care	This review now includes six studies, with a total of 1727 participants. Regarding participant outcomes, only one trial assessed the efficacy of a shared decision-making implementation strategy and found no impact on psychopathology, satisfaction with care, or drug attitude.
<i>BMC</i>	2018	The effects of shared decision-making compared to usual care for prostate cancer screening decisions: a systematic review and meta-analysis	Shared decision-making (SDM) is recommended for men facing prostate cancer (PC) screening decisions. We synthesize the evidence on the comparative effectiveness of SDM with usual care. We searched academic and grey literature databases, and other sources for primary randomized controlled trials (RCTs) published in English comparing SDM to usual care and conducted in primary and specialized care.
	2016	Implementing shared decision making in federally qualified health centers, a quasi-experimental design study: the Office-Guidelines Applied to Practice (Office-GAP) program	Use of SDM and Decision Aids has been encouraged but is not regularly implemented in primary care. The Office-Guidelines Applied to Practice (Office-GAP) intervention is an application of a previous model revised to address guidelines based care for low-income populations with diabetes and coronary heart disease (CHD). Objective: To evaluate Office-GAP Program feasibility and preliminary efficacy on medication use, patient satisfaction with physician communication and confidence in decision in low-income population with diabetes and CHD in a Federally Qualified Healthcare Center (FQHC).

	2013	“Many miles to go ...”: a systematic review of the implementation of patient decision support interventions into routine clinical practice	Two decades of research has established the positive effect of using patient-targeted decision support interventions: patients gain knowledge, greater understanding of probabilities and increased confidence in decisions. Yet, despite their efficacy, the effectiveness of these decision support interventions in routine practice has yet to be established; widespread adoption has not occurred. The aim of this review was to search for and analyze the findings of published peer-reviewed studies that investigated the success levels of strategies or methods where attempts were made to implement patient-targeted decision support interventions into routine clinical settings.
<i>Veterans Administration Evidence-based Synthesis Program</i>	2014	The Effects of Shared Decision Making on Cancer Screening	In this review we examine the effects of SDM interventions for cancer screening in adults on constructs from the Ottawa Decision Support Framework, a commonly-used theoretical model of decision making. We examined the constructs of Decision Quality, Decision Impact, and, for studies reporting those outcomes, Decision Action. Decision Quality includes knowledge, values clarity (patients' clarity of their personal values regarding the risks and benefits of decision options), and the patients' participatory role in decision making. Decision Impact includes decisional conflict (personal uncertainty about which course of action to take), use of services (e.g., consultation length), and satisfaction with the decision. Decision Action includes screening intention and behavior. The ideal SDM intervention would enhance Decision Quality (i.e., increase knowledge and values clarity) and Impact (i.e., increase satisfaction, reduce decision conflict, and have minimal impact on service utilization). The desired impact on Decision Action depends on the screening decision.

The Health Technology Assessment Program, Centers for Disease Control and Prevention, and the Institute for Clinical and Economic Review did not contain any relevant studies.

Appendix D: Shared Decision Making Categories

	Type	Stage	HCA Certification	Placement in Care Stream
Abnormal Uterine Bleeding	Procedural	III	No	Primary care Obstetrics/gynecology See 2018 Hysterectomy Report and Recommendations .
Advanced Care Planning	Other	I	CPR: advanced cancer (ACP Decisions) CPR: advanced disease (ACP Decisions) CPR: advanced heart failure (ACP Decisions) CPR: advanced liver disease (ACP Decisions) CPR: advanced lung disease (ACP Decisions) CPR: a closer look for people with a serious illness (ACP Decisions) Decisions about dialysis for patients 75 and older (ACP Decisions) Goals of care: advanced cancer (ACP Decisions) Goals of care: advanced dementia (ACP Decisions) Goals of care: advanced disease (ACP Decisions) Goals of care: advanced heart failure (ACP Decisions) Goals of care: advanced lung disease (ACP Decisions) Goals of care: family meetings in the ICU (ACP Decisions) Goals of care: skilled nursing facility (ACP Decisions) Hospice: advanced cancer (ACP Decisions) Hospice: skilled nursing facility (ACP Decisions) Hospice: an introduction (ACP Decisions) Supporting decisions involving extremely premature infants (ACP Decisions) Dementia for caregivers: goals of care: across the spectrum for Alzheimer's disease (ACP Decisions) CPR decision aid (Respecting Choices) Help with breathing decision aid (Respecting Choices) Long-term tube feeding decision aid (Respecting Choices) Medical care for serious illness (Health Dialog Services Corporation) Advanced lung cancer patient decision aid (Seattle Cancer Care Alliance)	Primary care Palliative care Oncology Others? See 2014 End-of-Life Care Report and Recommendations .
Attention Deficit Hyperactivity Disorder Treatment	Behavioral Health	III	No	Pediatrics, family medicine See 2016 Pediatric Psychotropic Use Report and Recommendations .
Breast Cancer Screening	Screening	III	No	Primary care

Depression Treatment	Behavioral Health	III	No	Behavioral Health See 2017 Behavioral Health Integration Report and Recommendations .
Knee and Hip Osteoarthritis	Procedural	I	Treatment choices for hip osteoarthritis (Health Dialog Services Corporation) Treatment choices for knee osteoarthritis (Health Dialogue Services Corporation) Hip osteoarthritis: is it time to think about surgery? (Healthwise) Knee osteoarthritis: is it time to think about surgery? (Healthwise) Is knee replacement surgery right for me? (Avaz Decisions) Is hip replacement surgery right for me? (Avaz Decisions)	Primary care Orthopedics See 2018 Total Knee and Total Hip Replacement Bundle and Warranty .
Opioid Use Disorder Treatment	Behavioral Health	IV	No	Primary Care Behavioral Health See 2017 Opioid Use Disorder Treatment Report and Recommendations .
Prostate Specific Antigen Testing	Screening	III	No	Primary Care Urology See 2015 Prostate Cancer Screening Report and Recommendations .
Spine Surgery (Lumbar Fusion)	Procedural	I	Spinal stenosis: choosing the right treatment for you (Health Dialogue)	Primary Care Orthopedics Neurosurgery See 2018 Lumbar Fusion Bundle and Warranty .
Trial of Labor After Cesarean Section	Procedural	I	Pregnancy: your birth options after cesarean (Healthwise) Pregnancy: birth options if your baby is getting too big (Healthwise)	Obstetrics care provider (i.e., obstetrics and gynecology, family medicine, or midwifery) See 2012 Obstetric Care Report and Recommendations .

Appendix D: Patient Decision Aid Certification Criteria

Developed by the Health Care Authority, October 1, 2017.

Does the patient decision aid adequately:

1. Describe the health condition or problem
2. Explicitly state the decision under consideration
3. Identify the eligible or target audience
4. Describe the options available for the decision, including non-treatment
5. Describe the positive features of each option (benefits)
6. Describe the negative features of each option (harms, side effects, disadvantages)
7. Help patients clarify their values for outcomes of options by a) asking patients to consider or rate which positive and negative features matter most to them AND/OR b) describing each option to help patients imagine the physical, social (e.g. impact on personal, family, or work life), and/or psychological effects
8. Make it possible to compare features of available options
9. Show positive and negative features of options with balanced detail
10. If outcome probabilities are included, allow comparison across options using the same denominator
11. Provide information about the funding sources for development
12. Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA
13. Include authors/developers' credentials or qualifications
14. Provide date of most recent revision (or production)
15. Follow plain language guidelines, to ensure understanding of people with low literacy and/or low health literacy skills

Additional Criteria for Screening and/Testing, if applicable:

16. Describe what the test is designed to measure
17. Describe next steps taken if test detects a condition/problem
18. Describe next steps if no condition/problem detected
19. Describe consequences of detection that would not have caused problems if the screen was not done
20. Include information about chances of true positive result
21. Include information about chances of false positive result
22. Include information about chances of true negative result
23. Include information about chances of false negative result

Does the Patient Decision Aid and/or the accompanying external documentation (including responses to the application for certification) adequately:

- Disclose and describe actual or potential financial or professional conflicts of interest?
- Fully describe the efforts used to eliminate bias in the decision aid content and presentation?
- Demonstrate developer entities and personnel are free from listed disqualifications?
- Demonstrate that the Patient Decision Aid has been developed and updated (if applicable) using high quality evidence in a systematic and unbiased fashion?
- Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool?
- Demonstrate that the patient decision aid or supporting document reports readability levels?

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