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Background

Definition

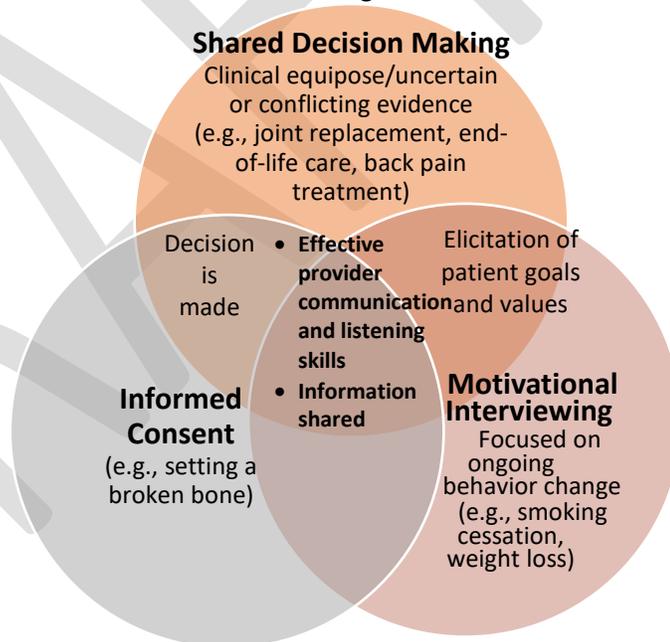
Shared decision making is a key component of patient-centered care, *“a process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences.”*¹ Shared decision making is appropriate for treatments, management options, or screenings that are: (1) preference-sensitive **and** (2) have high-quality clinical evidence for more than one option **or** (3) that have a lack of evidence and no clinical consensus on the best option (i.e., clinical equipoise). **To be effective, shared decision making must be supported by high-quality** communication between a provider and patient, and in some cases family members or others, about risks, benefits, and exploration of values and goals.

The process of shared decision making and the necessary clinical skills are complementary **to those needed for informed consent** and motivational interviewing. In all cases information is shared and a decision is made that is supported by clinical **evidence, requiring** effective provider communication and listening skills. Shared decision making assumes an uncertain goal due to clinical equipoise and requires the patient and the clinician to share the process of arriving at the decision.

The goal of motivational interviewing is typically behavior change requiring an understanding of the patient’s motivations and barriers to change; an example being smoking cessation. As with informed consent, there can be provider advocacy for a specific approach if supported by evidence. See Figure 1, for a graphic outlining the differences and similarities between shared decision making, informed consent, and motivational interviewing and Appendix X, for more detailed language.

As with all clinical choices, patients should also know that deciding not to have an intervention or test is also an option.

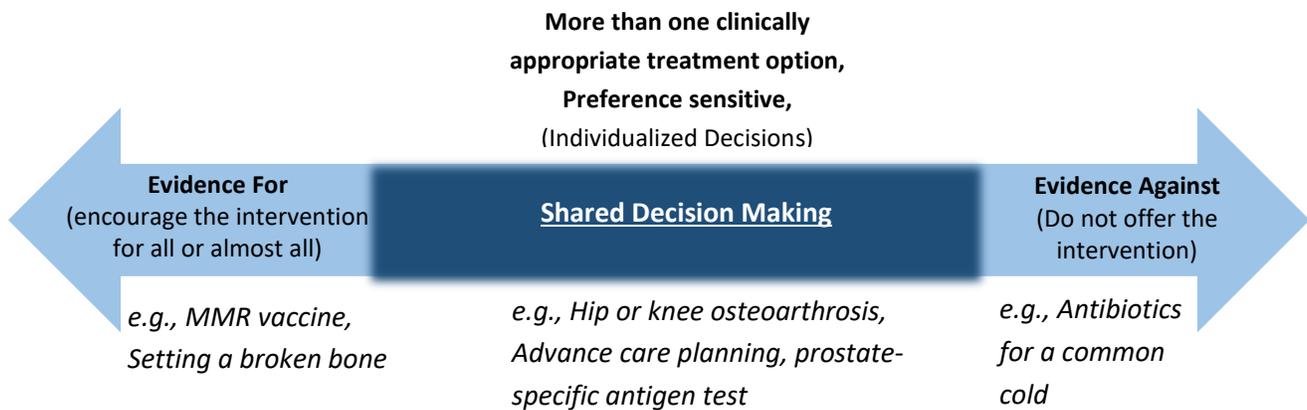
Figure 1: Shared Decision Making, Informed Consent and Motivational Interviewing



Clinical Appropriateness

Shared decision making is not appropriate when there is clear evidence for **net benefit or harm from one intervention relative to others**, such as for immunization against measles mumps or rubella (MMR) or against antibiotics for a common cold; see **Figure 2 below**. **Due to clear evidence, the clinician has a pre-determined goal and may use motivational interviewing to bring the patient encourage the patient to make choices in-line with this goal. Regardless of the option chosen, the patient should receive informed consent of the treatment or non-treatment chosen.**

Figure 2: Appropriateness of Shared Decision Making²



Essential components of shared decision making include: clinical knowledge and perspective, likelihood of risks and benefits, the patient’s informed preferences, and in many cases, a decision aid that helps provide objective information and designates the patient as decision-maker. A 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. At an organizational level, a patient decision aid is necessary for reliability of delivering high-quality shared decision making and can greatly enhance the process, but is not essential for shared decision making to take place. **The care team should also be trained on shared decision making and how to use a patient decision aid.** Where possible, the workgroup encourages shared decision making with a patient decision aid but as these aids are only available for a small number of procedures, the lack of an aid should not prohibit a conversation using a shared decision framework.

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.³ The process has also been associated with improved patient satisfaction with care, improved health outcomes, and with better appropriateness of care.^{4,5} **In most cited examples, shared decision making is done with a patient decision aid.** 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; **examples include** increasing rates of total knee replacement for black patients with osteoarthritis of the knee to rates closer to **those** of white patients.⁶

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 **perception that the process adds time to the clinical encounter**, providers being overworked, lack of training, lack of structural support including through electronic health records and clinic general workflow, fear of revenue loss if **procedure rates decrease, expense of decision aids**, and decision aids themselves not being applicable to the specific patient's characteristics or not being applicable to the specific clinical situation.^{7,8} Having a supportive clinical culture is paramount **for** successful implementation, starting with engaged leadership.⁹ 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 patient 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.¹⁰ Shared decision-making or use of patient decision aids has 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.

Recommendation Framework

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). Some organizations will be starting in the precontemplation phase (e.g., needing 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. **Note that other change management models can also be used to support implementation. Regardless of the model used, implementing shared decision making requires system-level change and a change management rubric should be used to enable this process.**

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 an initial focus for the health care community
- **Highly reliable implementation using an existing framework customized to an individual organization**
- 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, 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., family medicine).

See **Appendix X** for a detailed list of these ten areas:

- Abnormal Uterine Bleeding (procedural)
- Advance Care Planning
- Attention Deficit Hyperactivity Disorder Treatment (behavioral health)
- Breast Cancer Screening (screening)
- Depression Treatment (behavioral health)
- Knee and Hip Osteoarthritis (procedural)
- Opioid Use Disorder Treatment (behavioral health)
- Prostate Specific Antigen Testing (screening)
- Spine Surgery (Lumbar Fusion) (procedural)
- Trial of Labor After Cesarean Section (procedural)

Shared Decision Making – DRAFT

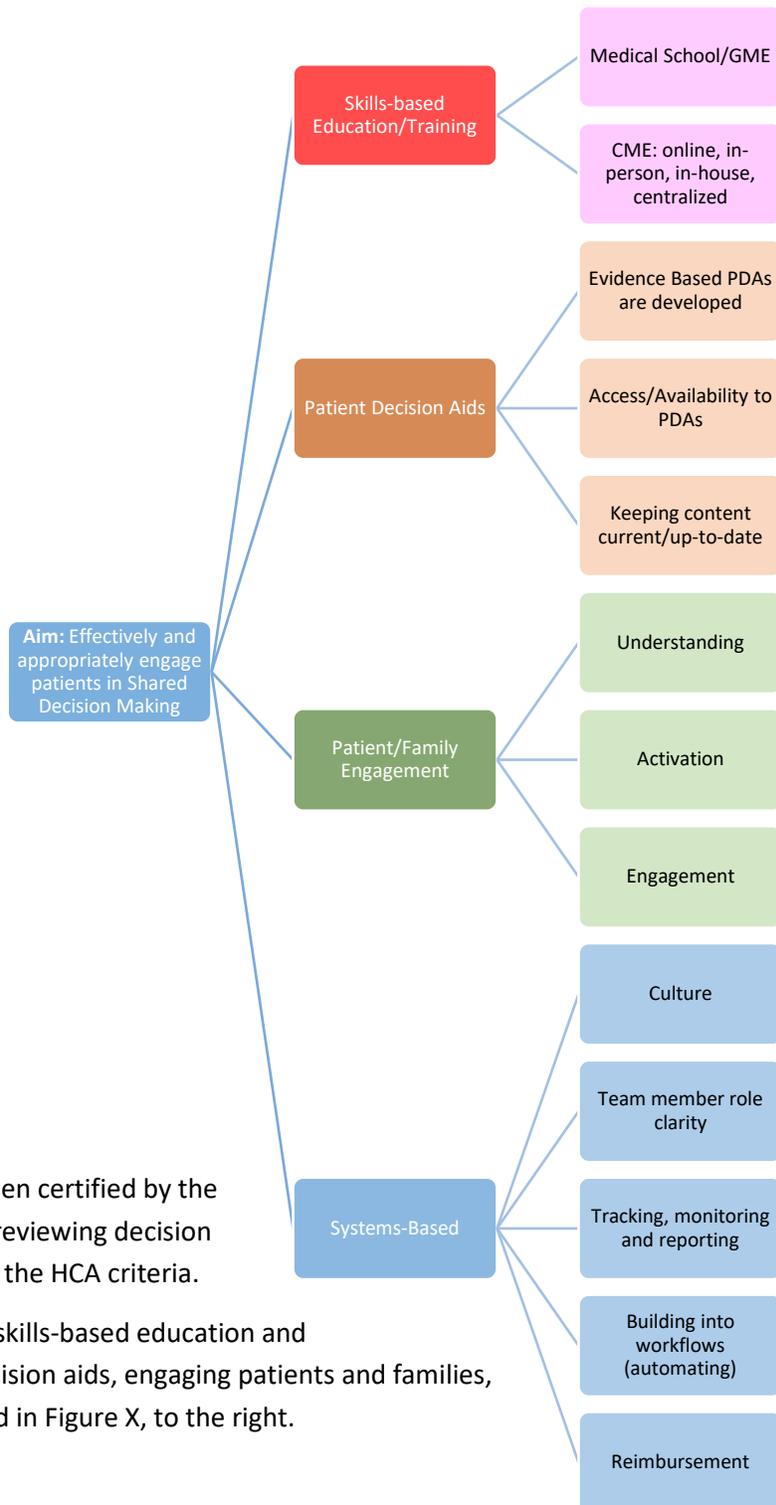
Updated: August 22, 2019

The Washington State Health Care Authority (HCA) has worked to certify patient decision aids since April 2016.¹¹ 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.¹² The HCA has certified patient decision aids for knee and hip osteoarthritis, advance care planning, obstetrics (e.g., trial of labor after cesarean section, birth options for large babies), **cardiology**, and 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 Stakeholders

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

Patients and Family Members

- Think about the role you want to have in making your medical decisions. Review the background listed in the report and figure X on page X to see where shared decision making should be used.
 - For treatments or tests that are preference-sensitive, do you want to share your preferences and concerns with your clinical team, or would you rather just follow their advice?
- If you want to engage in shared decision-making, ask your provider to have a shared decision making conversation with you. Ask whether a patient decision aid is available.
- Ask your care provider about the test or treatment options available, including the option of “doing nothing” or “watchful waiting.”
 - Ask about the expected outcomes of the various options, including the option of “watchful waiting” and how likely you are to experience the benefits and risks of each option.
 - Ask questions to be sure you understand your choices.
 - Share your concerns and preferences.
- Remember that some medical decisions don’t need to be made right away. Find out if you need to decide right away, or can take time to think about it or talk it over with others. Find out if you can change your decision in the future, such as doing nothing now, and revisiting the decision later.

Patient Advocates and Community Organizations

- Educate patients about the value of shared decision making, and support empowering them to request shared decision making.
- Educate communities about the impact of shared decision making on health outcomes and health equity.
- Identify specific areas where shared decision making can be used to address community needs (e.g., underutilization of screening in a minority community) and work with provider groups to implement changes.

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.
- Implement the skills learned in training, and identify reminders or other methods to maintain these practices.
- Actively recommend and use high quality decision aids with your patients.

- Document use of shared decision making in the medical record, see page X.

Health Care Delivery Organizations and Systems

- Identify where you are as an organization in the stages of change for shared decision making.

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 advance 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, and administrative champion to support necessary operational changes. • 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. • 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 other sites or adopt shared decision making within another clinical area.

- Review new evidence on a regular basis to update the shared decision making options based on the most current evidence.

Provider Associations

- Support shared decision making skills as an important component of patient care.
- Increase awareness of and education about shared decision making through newsletters, web sites, and potentially CME opportunities.
- Gather information about providers' experience of shared decision making efforts and use these to support improvements.

Health Plans and Professional Liability Carriers

- Reimburse for and/or incentivize use of shared decision making and patient decision aids, including the 10 topic areas, in fee for service reimbursement.
- Incorporate shared decision making requirements as standards for value-based models (e.g., Centers of Excellence).
- Incorporate metrics around shared decision making into standard reporting (see page X).
- Consider providing a range of high-quality decision aids to providers and patients online.
- Require shared decision making, where appropriate, as a prior authorization requirement for high-risk, high-cost approaches to preference sensitive conditions.
- Consider supporting continuing education on shared decision making for clinicians.
- Provide discounts or other incentives for professional liability coverage for providers trained in and actively engaging in shared decision making.

Employers

- Incorporate shared decision making requirements as standards for value-based contracting (e.g., Centers of Excellence, accountable care programs).
- Talk to your health plan about the importance of shared decision making and how to report on use of shared decision making including how to ensure appropriate reimbursement.
- Support patient education about treatment choices and shared decision making through patient-facing materials (e.g., newsletters) and wellness programs.
- Provide access to patient decision aids.

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 remainder of the ten priority 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.
- Where possible, identify and use metrics and payment methodologies that can be adopted by other payers to facilitate spread.

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.¹³ 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](#)

Documentation, Coding, and Reimbursement

Shared decision making should be documented like any other clinical encounter. While there are some limited existing codes (e.g., G0296 Counseling), the workgroup recommends additional coding for added shared decision making reimbursement. Some payers require evidence of shared decision making in order to proceed with next steps and shared decision making is included as part of some alternative payment models (e.g., total joint replacement bundles).

Documentation

Important roles of documentation include:

- Documenting elements required for legal protection, see the following section.
- Demonstrating and reinforcing adherence to a high-fidelity shared decision making model and its attendant components.
- Facilitating data capture and tracking of shared decision making use for quality and payment purposes.

In keeping with these roles, recommendations for documentation include:

- Adoption of standardized language for shared decision making documentation at the broadest system level possible, to be used for all shared decision making events.
- Inclusion of all elements noted in the RCW, above. See sample language in the next section.
- When possible, incorporation of the standardized language into an automated electronic health record template (“smartphrase” or similar) for consistency and ease of provider implementation
- When possible, use of an element that allows use of the standardized language to be captured by the electronic health record (a “flag”), for easy identification and tracking of shared decision making use.

Coding

Coding enables tracking of shared decision making use and facilitates incorporation of shared decision making reimbursement. This can occur in several ways:

- When shared decision making is appropriate as a component of prior authorization (i.e., high-risk, high-cost interventions for preference sensitive conditions, such as spinal fusion or left atrial appendage closure), coding of the activity enables efficient capture by the insurance carrier for approval (see CMS example below).
- When shared decision making is used as a quality measure within value-based contracts, coding enables population-level data capture without the complexity and expense of electronic health record extraction.

Examples of documentation within CMS include:

- 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) ≤ 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.¹⁴
- 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).¹⁵

Fee for Service Reimbursement

Fee for service (FFS) payment could be done using existing evaluation and management (E&M) coding, reimbursing for time for “*counseling and coordination of care,*” can include shared decision making. This has the advantage of simplicity and immediate implementation under existing structures. Adding an element of “XX minutes of face-to-face time, the majority spent in counseling and coordination of care” to the standardized shared decision making documentation template would facilitate this.

Alternately, a specific code(s) could be developed for billing and reimbursement of shared decision making, as has been done for advance care planning.

Value-Based Reimbursement

Shared decision making could be incorporated into value-based arrangements in a number of ways. When shared decision making is required as part of a bundled payment, such as for a center of excellence model, then the organization providing the service would need to attribute a component of payment to the deliverer of shared decision making. Similarly, if shared decision making were required as a prior authorization component for certain procedures (e.g., spinal surgery), the proceduralist could perform the shared decision making themselves or reimburse another provider for doing so. These contracts internal to the risk-bearing entity (e.g., a hospital) are determined by that entity.

If shared decision making metrics were incentivized under pay-for-performance arrangements, provider systems could use incentive payments to fund shared decision making. For Accountable Care Organizations, shared decision making would be expected to have a positive impact on member experience, clinical outcomes, and utilization, all of which should increase profitability for the Accountable Care Organization sufficiently to justify investment.

Examples for Medicaid via CMS include:

- CMS presented a model focused on shared decision making that has since been cancelled.¹⁶ 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.¹⁷ 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 shared decision making claim, operational data (e.g., total number of decision aids given, engagement rate for shared decision making model), and beneficiary questionnaire data (i.e., questionnaire beneficiary completes after shared decision making process).

Communication and Patient Satisfaction

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 risks and likelihood of positive outcomes 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.¹⁸ Aside from 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.

Reducing Liability

An established rapport between the patient and the physician based on solid exchanges of information reduces litigation risk. Shared decision making encourages rapport and a two-way flow of information, decreasing the likelihood of perceived communication failures and failure to adequately talk about risks that matter to patients.

Washington State sought to encourage shared decision making and 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.*"ⁱ 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 cardiac care.¹⁹ More topics are in the pipeline, and are expected to be aligned with Bree Collaborative recommendations.

ⁱ 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.

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 their preferences. This makes litigation less likely and provides a higher standard that the patient needs to meet.

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.

Documentation

Washington state law outlines how providers can document shared decision making 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. See **Appendix Appendix G**: Revised Code of Washington 7.70.060 Shared Decision Making Language.

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

Options for tracking shared decision making are below:

- **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 6months, 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 A: Bree Collaborative Members

Member	Title	Organization
Susie Dade, MS	Deputy Director	Washington Health Alliance
Peter Dunbar, MB ChB, MBA (Vice-Chair)	CEO	Foundation for Health Care Quality
Gary Franklin, MD, MPH	Medical Director	Washington State Department of Labor and Industries
Stuart Freed, MD	Chief Medical Officer	Confluence Health
Richard Goss, MD	Medical Director	Harborview Medical Center – University of Washington
Sonja Kellen	Global Benefits Director	Microsoft
Dan Kent, MD	Chief Medical Officer, Community Plan	UnitedHealthcare
Wm. Richard Ludwig, MD	Chief Medical Officer, Accountable Care Organization	Providence Health and Services
Greg Marchand	Director, Benefits & Policy and Strategy	The Boeing Company
Robert Mecklenburg, MD	Medical Director, Center for Health Care Solutions	Virginia Mason Medical Center
Kimberly Moore, MD	Associate Chief Medical Officer	Franciscan Health System
Carl Olden, MD	Family Physician	Pacific Crest Family Medicine, Yakima
Drew Oliveira, MD	Executive Medical Director	Regence BlueShield
Mary Kay O’Neill, MD, MBA	Partner	Mercer
John Robinson, MD, SM	Chief Medical Officer	First Choice Health
Jeanne Rupert, DO, PhD	Provider	One Medical
Angela Sparks, MD	Medical Director Clinical Knowledge Development & Support	Kaiser Permanente Washington
Hugh Straley, MD (Chair)	Retired	Medical Director, Group Health Cooperative; President, Group Health Physicians
Shawn West, MD	Medical Director	Premera BlueCross
Laura Kate Zaichkin, MPH	Director of Health Plan Performance and Strategy	SEIU 775 Benefits Group
Judy Zerzan, MD, MPH	Chief Medical Officer	Washington State Health Care Authority

Appendix B: Shared Decision Making Charter and Roster

Problem Statement

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. The Washington State Health Care Authority defines shared decision making as “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.”ⁱⁱ Shared decision making for preference-sensitive conditions has been shown to improve patient satisfaction with care, health outcomes, and appropriateness of care.^{iii,iv}

Aim

To recommend policies and clinical pathways for widespread adoption of shared decision making across the country.

Purpose

To propose evidence-based, actionable, practical recommendations to the full Bree Collaborative on:

- A Washington state-specific shared decision making toolkit.
- Building on the work of the 2018 thought leader group.
- Leveraging and adapting the National Quality Forum shared decision making playbook and previous Bree Collaborative recommendations.
- Addressing barriers and recommending enablers for shared decision making adoption and sustainable use.
- Providing guidance and support for cross-sector implementation activities.
- Identifying other areas of focus, funding opportunities, or modifying areas, as needed.

Duties & Functions

The Shared Decision Making workgroup will:

- Research evidence-based and expert-opinion informed guidelines and best practices (emerging and established).
- Consult relevant professional associations and other stakeholder organizations and subject matter experts for feedback, as appropriate.
- Meet for approximately nine months, as needed.
- Provide updates at Bree Collaborative meetings.
- Post draft report(s) on the Bree Collaborative website for public comment prior to sending report to the Bree Collaborative for approval and adoption.
- Present findings and recommendations in a report.
- Recommend data-driven and practical implementation strategies.
- Create and oversee subsequent subgroups to help carry out the work, as needed.
- Revise this charter as necessary based on scope of work.

ⁱⁱ Washington State Health Care Authority. Shared Decision Making. 2018. Accessed: November 2018. Available: www.hca.wa.gov/about-hca/healthier-washington/shared-decision-making.

ⁱⁱⁱ Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. *Health Aff (Millwood)*. 2012 Sep;31(9):2094-104.

^{iv} Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014 Jan 28;(1):CD001431.

Structure

The workgroup will consist of individuals confirmed by Bree Collaborative members or appointed by the chair of the Bree Collaborative or the workgroup chair. The chair of the workgroup will be appointed by the chair of the Bree Collaborative. The Bree Collaborative program director and program assistant will staff and provide management and support services for the workgroup.

Less than the full workgroup may convene to: gather and discuss information; conduct research; analyze relevant issues and facts; or draft recommendations for the deliberation of the full workgroup. A quorum shall be a simple majority and shall be required to accept and approve recommendations to send to the Bree Collaborative.

Meetings

The workgroup will hold meetings as necessary. The director will conduct meetings along with the chair, arrange for the recording of each meeting, and distribute meeting agendas and other materials prior to each meeting. Additional workgroup members may be added at the discretion of the chair.

Name	Title	Organization
Emily Transue, MD, MHA (Chair)	Associate Medical Director	Washington State Health Care Authority
David Buchholz, MD	Medical Director	Premera
Sharon Gilmore, RN	Risk Consultant	Coverys
Leah Hole-Marshall, JD	General Counsel and Chief Strategist	Washington Health Benefit Exchange
Steve Jacobson MD, MHA, CPC	Associate Medical Director, Care Coordination	The Everett Clinic, a DaVita Medical Group
Dan Kent, MD	Medical Director	United Health Care
Andrew Kartunen	Program Director, Growth and Strategy	Virginia Mason Medical System
Dan Lessler, MD	Physician Executive for Community Engagement and Leadership	Comagine Health
Jessica Martinson, MA	Director of Clinical Education and Professional Development	Washington State Medical Association
Karen Merrikin, JD	Consultant	Washington State Health Care Authority
Randy Moseley, MD	Medical Director, Quality	Confluence Health
Michael Myint, MD	Medical Director, Population Health	Swedish Hospital
Martine Pierre Louis, MPH	Director, Interpreter Services	Harborview Medical Center
Karen Posner, PhD	Research Professor, Laura Cheney Professor in Anesthesia Patient Safety	Department of Anesthesiology & Pain Medicine, University of Washington
Angie Sparks, MD	Family Physician and Medical Director, Clinical Knowledge Development	Kaiser Permanente of Washington
Anita Sulaiman	Patient Advocate	

Appendix C: Guideline and Systematic Review Search Results

	<i>Year</i>	<i>Title</i>	<i>Summary</i>
<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 shared decision making 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 shared decision making 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 shared decision making 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 shared decision making 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 people with mental health conditions	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 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 shared decision making 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 shared decision making 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	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

	about mode of birth after a caesarean	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 behavior for acute respiratory infections in primary care: an overview of systematic reviews	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 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.

<p>BMC</p>	<p>2018</p>	<p>The effects of shared decision-making compared to usual care for prostate cancer screening decisions: a systematic review and meta-analysis</p>	<p>Shared decision-making (shared decision making) is recommended for men facing prostate cancer (PC) screening decisions. We synthesize the evidence on the comparative effectiveness of shared decision making with usual care. We searched academic and grey literature databases, and other sources for primary randomized controlled trials (RCTs) published in English comparing shared decision making to usual care and conducted in primary and specialized care.</p>
	<p>2016</p>	<p>Implementing shared decision making in federally qualified health centers, a quasi-experimental design study: the Office-Guidelines Applied to Practice (Office-GAP) program</p>	<p>Use of shared decision making 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).</p>
	<p>2013</p>	<p>“Many miles to go ...”: a systematic review of the implementation of patient decision support interventions into routine clinical practice</p>	<p>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.</p>

<p><i>Veterans Administration Evidence-based Synthesis Program</i></p>	<p>2014</p>	<p>The Effects of Shared Decision Making on Cancer Screening</p>	<p>In this review we examine the effects of shared decision making 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 shared decision making 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.</p>
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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	HCA Certification	Placement in Care Stream
Abnormal Uterine Bleeding	Procedural	No	Primary care Obstetrics/gynecology See 2018 Hysterectomy Report and Recommendations.
Advance Care Planning	Other	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 See 2014 End-of-Life Care Report and Recommendations.
Attention Deficit Hyperactivity Disorder Treatment	Behavioral Health	No	Pediatrics, family medicine See 2016 Pediatric Psychotropic Use Report and Recommendations.
Breast Cancer Screening	Screening	No	Primary care
Depression Treatment	Behavioral Health	No	Behavioral Health

			See 2017 Behavioral Health Integration Report and Recommendations .
Knee and Hip Osteoarthritis	Procedural	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	No	Primary Care Behavioral Health See 2017 Opioid Use Disorder Treatment Report and Recommendations .
Prostate Specific Antigen Testing	Screening	No	Primary Care Urology See 2015 Prostate Cancer Screening Report and Recommendations .
Spine Surgery (Lumbar Fusion)	Procedural	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	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 E: Shared Decision Making, Informed Consent, and Motivational Interviewing

	<i>Informed Consent</i>	<i>Shared Decision Making</i>	<i>Motivational interviewing</i>
<i>Primary/ultimate goal</i>	Patient understanding of risks and benefits of a selected option before agreeing to proceed	A decision between clinically appropriate options driven by patient values and made in collaboration between provider and patient.	Behavioral change achieved through identifying patient values and motivators and using these to drive progress toward a desired health outcome.
<i>Clinical setting/scenario</i>	Prior to agreeing to any intervention with risks and benefits	Clinical equipoise exists among multiple options, with different impacts on different values	A patient's choices or behaviors are incongruous with desired health outcomes.
<i>Additional context</i>	Ethically and legally, a patient must be aware of risks and benefits in order to agree to treatment. This is true whether there are multiple reasonable options (treating chronic back pain) or only one (setting a severely broken bone).	Given clinical equipoise, the provider's beliefs and values should not drive toward a specific choice; rather, the provider's role is to explain options relative to the patient's values and help them make the decision that is best for them.	This can occur because of a lack of understanding of the impact of these choices, competing values and priorities, or other reasons; the clinician attempts to identify and reconcile these conflicts to achieve desired goals. The patient and provider may or may not agree on proximate goals (smoking cessation, weight loss, vaccine administration), but should agree on ultimate goals (good health and quality of life), and find shared ground in connecting these.
<i>Classic examples</i>	Starting a medication; setting a broken bone; any surgery.	Joint replacement; end of life care; approaches to back pain.	Smoking cessation; weight loss.
<i>Shared elements:</i>			
<i>Effective provider communication</i>	+++	+++	+++
<i>Elicitation of patient values and priorities</i>	+	+++ (used to drive decision about treatment)	+++ (used to drive behavior change)
<i>Providing information about risks and</i>	++ (primary focus is on selected option)	+++	+ (primary focus is on desired option)

<i>benefits of all options</i>			
<i>Listening skills including active listening (eliciting patient's understanding after information given, etc)</i>	+++ (in reality, often poorly performed but necessary to true informed consent)	+++	+++
<i>Distinct elements</i>			
<i>Clinical equipoise</i>	Not required	Required	Not required
<i>Provider advocacy for a specific approach</i>	May be present, but should not interfere with giving full and accurate data	Absent: not appropriate given clinical equipoise	May be present if evidence supports a specific approach. Provider and patient may strongly disagree on best course of action; in this case the provider's role is to identify patient values/motivators that make them more likely to select this approach.

Appendix F: 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?

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- 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?

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.*

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