



SHARED DECISION MAKING: ADVANCING PATIENT-CENTERED CARE THROUGH STATE AND FEDERAL IMPLEMENTATION

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MARCH 2012



INFORMED MEDICAL
DECISIONS FOUNDATION

Partnerships for Quality Care

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ACKNOWLEDGMENTS

The authors wish to thank the Informed Medical Decisions Foundation for providing an educational grant to support this project, and particularly Ben Moulton for lending his guidance and expertise to the development of this report. We also thank the many key informants and reviewers of report drafts, who provided insights that helped inform our work, including the members of the project advisory group and meeting participants, listed in Appendix A. We would like to particularly thank Dawn Stacey for her contributions to the research and careful review of draft documents to ensure that the report builds upon her previous work. Finally, we thank Larry Hinkle and Mary Henderson at NASHP for assistance with project, meeting, and document preparation.

EXECUTIVE SUMMARY

Shared decision making (SDM) is a strategy that is receiving increased attention as providers, purchasers, policymakers, and consumers explore opportunities to integrate patient-centered concepts into standards of care. It is a process undertaken between providers and a patient with a condition with more than one clinically appropriate management strategy to help the patient decide among multiple acceptable health care choices in accordance with their preferences and values. Decision aids are used to facilitate the SDM process. Patients typically view a decision aid for their condition and then have a discussion with their provider or an inter-professional team of providers about their health care options and determine the health care choice that best matches their values and preferences.

SDM facilitated with decision aids holds promise for improving quality, reducing unwarranted variation in care, and improving patient satisfaction. Numerous studies have found that using patient decision aids improves knowledge of health care choices, increases the proportion of patients with realistic perceptions of benefits and harms, lowers decisional conflict, reduces the number of patients that are passively involved in decision making, reduces the number of patients undecided after counseling, and improves agreement between patient values and the health care option chosen.¹ Health policy researchers also hypothesize that SDM may reduce over-diagnosis and over-treatment and thereby reduce costs.² For example, an initial cost analysis of implementing SDM for 11 procedures estimates the savings to national health spending to be greater than \$9 billion over ten years.³

In October 2011, NASHP convened a meeting of state and federal officials, SDM experts, and consumer, provider, and purchaser representatives to discuss the opportunities and challenges for state implementation of SDM and the lessons from state experience that can be applied to federal implementation. NASHP synthesized background information and interviewed leading state officials to produce a background paper that was augmented by lessons discussed during the stakeholder meeting to inform this report.

States that have implemented or considered implementing SDM have used a variety of approaches to incorporate SDM into state policy, including legislation, public-private partnerships and collaborations, and incorporation into state standards and expectations (e.g. medical home or Accountable Care Organizations (ACOs)). Highlights of state activity in Maine, Minnesota, Oregon, Vermont, and Washington are included in the report. Most of these states pursued multiple approaches to implement SDM, such as using public-private partnerships to provide guidance to demonstration projects mandated by legislation, or incorporating SDM into informed consent guidelines in addition to planning ACO demonstration projects.

The main challenges states face in implementing SDM are the lack of national certification of decision aids, creating an operating definition of SDM for their state or project, provider resistance, provider engagement, and measurement of implementation progress. In order to improve quality and utilization metrics, states looking to address these challenges can build on the experiences of others that have implemented SDM, including the experience of Group Health Cooperative in Washington, which has conducted the largest SDM demonstration project. They can also leverage federal activity related to SDM, including opportunities both within and external to national health reform.

There are numerous steps that interested states can take in advancing and implementing SDM. There are six main recommendations outlined in this report.

- Build SDM into current momentum to transform the health care delivery system.
- Identify procedures with significant variation in utilization rates according to state data or state-

specific Dartmouth Atlas analysis, and consider state legislation to promote pilot projects for these procedures.

- Capitalize on state roles as purchasers, regulators, conveners, and educators.
- Use a multi-faceted approach in collaboration with private partners.
- Engage providers as partners throughout the SDM process, providing adequate training, and using provider expertise to integrate SDM into the care process.
- Implement SDM in an integrated system if available; if not, implement in a fee-for-service system.

States and health systems have many choices to make when implementing SDM. Though the choices are not simple, states can customize SDM to their specific situations to best benefit existing quality and strategic initiatives.

States can also take advantage of federal opportunities that promote SDM. SDM has already been incorporated into federal rules for ACOs, and states can partner with organizations that applied for the Health Care Innovation Challenge in January 2012, which supported shared decision making as a model of infrastructure funding. If states capitalize on opportunities, partner with organizations with expertise, and draw on important lessons from leading states, they can maximize the use of SDM as a tool to improve quality, reduce unwarranted variation in care, and improve patient satisfaction to meet their health care transformation goals.

INTRODUCTION

The quality of health care in the United States has come under increased scrutiny in the past decade as patients fail to consistently receive evidence-based care that meets their needs. Among other issues, there are shortfalls in patient safety, fragmented delivery systems, and inappropriate utilization of care. The Institute of Medicine has recommended redesigning the health care system to improve the quality of care, and has defined quality as care that is safe, effective, patient-centered, timely, efficient, and equitable.⁴

A variety of initiatives—nationally and at the state level—are underway to address the shortfalls in patient care and the delivery system, and to improve health care quality. States are leading efforts to coordinate quality improvement strategies through public–private partnerships and integrating their efforts into broader state health care reform agendas.⁵ States are using strategies such as data collection and standardization, data transparency and public reporting, payment reform, and consumer and provider engagement.⁶ They are also increasingly incorporating medical homes or ACOs into their health reform efforts and state health care programs to provide more patient-centered, coordinated, and efficient care.⁷

Shared decision making (SDM) is one strategy receiving increased attention as providers, purchasers, policymakers, and consumers explore opportunities to integrate patient-centered concepts into standards of care. SDM—a process that engages patients in a dialogue with their providers to help them select health care options that conform to their values and preferences—not only honors patient participation in decisions but also holds promise for improving quality, reducing unwarranted variation in care, and improving patient satisfaction. Health policy researchers hypothesize SDM may reduce over-diagnosis and over-treatment and thereby reduce costs.⁸ This report reviews the definition and process of SDM, the evidence and rationale to explore its implementation, and the potential roles of states in promoting SDM. This report also discusses the challenges of implementing SDM, state strategies to overcome these challenges, the policy options states have pursued, and lessons from their experience. The experiences of leading states can inform additional states that are considering SDM and provide guidance to the federal government as it implements provisions of the Affordable Care Act related to SDM and final regulations that incorporate SDM into the rules for Accountable Care Organizations (ACOs).

PROJECT METHODOLOGY

In October 2011, NASHP convened a meeting of state and federal officials, SDM experts, and consumer, provider, and purchaser representatives to discuss the opportunities and challenges for state implementation of SDM and the lessons from state experience that can be applied to federal implementation. NASHP synthesized background information and interviewed leading state officials to produce a background paper augmented by lessons discussed during the stakeholder meeting. Appendix A lists key informants who participated in the project.

WHAT IS SHARED DECISION MAKING?

Shared decision making (SDM) is a process undertaken between providers and a patient with a preference-sensitive condition—a condition where there is more than one clinically appropriate intervention or management strategy—to help the patient decide among multiple acceptable health care choices in accordance with their preferences and values. SDM goes beyond traditional informed consent in which risks, benefits, alternatives, and weighing of probabilities are discussed; SDM also helps identify the patient's individual values and preferences for the risks, benefits, and probabilities of various possible outcomes.

The patient's condition is considered preference sensitive since each health care option has varying benefits and harms, and ideally, the patient's health care choice should be aligned with their values and preferences and perception of these tradeoffs. For example, in early stage breast cancer, the survival rates and life expectancy are similar for both lumpectomy followed by radiation therapy, and mastectomy.⁹ Thus, a patient's treatment choice would be dependent on whether she more strongly valued retaining her breast and removing the tumor with a lumpectomy, or whether she preferred to decrease the chances of local recurrence by removing her breast completely with a mastectomy. Similarly, there are multiple options for early stage prostate cancer, such as conservative management, surgery, or radiation. The patient's decision depends on his preference to either treat the cancer or do "watchful waiting" if he wishes to avoid potential complications of a surgery such as impotence and incontinence. End-of-life decisions, such as whether to elect for cardiopulmonary resuscitation or artificial nutrition, are also considered preference sensitive.

Patient decision aids are tools that assist and guide patients through the decision-making process and are used to facilitate SDM. The patient often views a decision aid for their condition prior to having a discussion with their provider or an inter-professional team of providers to discuss their health care options and determine the health care choice that best matches the patient's values and preferences. Decision aids differ from typical health education materials because they explicitly state the decision to be made and have a "detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making."¹⁰ Decision aids vary slightly and come in a variety of media forms, from pamphlets to interactive websites, but in general they:

1. Provide evidence-based information about a health condition, health care options, and the associated benefits, harms, and probabilities with each option;
2. Help patients clarify their values and determine what is most important to them with regards to benefits and harms;
3. Provide structured guidance in the steps of a decision-making process, often by asking sequential questions that identify the patient's preferences.¹¹

Decision aids can also contain patient narratives or videotaped interviews with patients who made various health care decisions, explaining their reasons for pursuing the health care option they did and their thoughts on the health care they chose.

Shared Decision Making Terminology

- *Clinically appropriate patient:* A patient who meets all the clinical criteria necessary to qualify for a test or procedure, i.e., the recommended age for a screening exam, or the physiological changes qualifying a patient for a knee replacement.
- *Preference-sensitive condition:* A condition with more than one clinically appropriate intervention or management strategy, each with varying benefits and drawbacks, and where the patient's values and preferences should be critical in determining the chosen intervention.
- *Patient decision aid:* Tools that help assist and guide patients with the decision-making process through a detailed focus on options and outcomes. Patient decision aids are available in a variety of media, such as pamphlets, DVDs, and interactive websites or videos.

Shared decision making is a process that occurs between patients and their providers. Decision aids are not meant to replace a clinician’s input, but rather to supplement a clinician’s counseling. Providers’ contributions to the decision include their medical knowledge of the condition, likely prognosis, and health care options and likely outcomes; patients “know about the impact of the condition on their daily life, and their personal attitude to risk, values and preferences.”¹² SDM allows for greater patient engagement by formalizing this process through the use of decision aids and the acknowledgment of the importance of patient values and preferences. This process can differ among care settings as to when a decision aid is distributed to the patient, and whether a nurse or care navigator assists the patient with the decision process or if the patient speaks primarily to a physician.

There are broader conceptualizations of SDM meant to capture the intent of SDM to involve the patient as a partner in care with their physician.¹³ In this report, we have chosen to limit our discussion of SDM to methods that include the use of a decision aid to emphasize the link between standardized decision aids and SDM. We have chosen this definition since decision aids help provide standardized, researched and structured information to patients. Ideally, however, broader adoption of SDM will push providers to routinely consider patient values and preferences.

THE NEED FOR SDM

SDM has received increased attention as a strategy for patient engagement and as a tool in quality initiatives aimed to address variation in procedure utilization. The Dartmouth Atlas — a research project based at Dartmouth College that documents variation in medical resource distribution and use — has documented significant variations in the rate of certain surgical procedures across the country, especially for preference-sensitive conditions such as joint replacements or low back pain. Ten common preference-sensitive conditions account for approximately 40 percent of Medicare spending on inpatient surgery.¹⁴ Among 306 U.S. Hospital Referral Regions in 2002-2003, the incidence of joint replacement for chronic arthritis of the hip and knee was approximately five times higher in one region compared to another, and surgery for low-back pain varied 5.9-fold.¹⁵ This variation has also been documented for treatments for early stage breast cancer, Benign Prostatic Hyperplasia (BPH), early stage prostate cancer, and certain cardiac treatments.^{16, 17} These variations suggest that patients may not receive care that aligns with their preferences. Past research has shown that many patients that meet clinical guidelines for appropriateness choose not to have surgical procedures once they are fully informed of their treatment options.¹⁸ For this reason, policy makers expect that use of SDM will reduce—but not eliminate—the high level of variation. They also hope it will improve patient-centered care and prevent preference-sensitive procedures from being performed in circumstances where, if informed with balanced evidence-based information and if personal preferences were taken into account, the patient would have chosen a different health care option.

One of the most significant recommendations for use of SDM as an integral part of quality initiatives has been the inclusion of SDM principles in the Institute of Medicine’s *Crossing the Quality Chasm* report. The IOM recommends that health care processes should be redesigned in accordance with ten rules. SDM principles appear in three:

1. Shared knowledge and free flow of information, which recommends that clinicians and patients should communicate effectively and share information;
2. Evidence-based decision making, which states that patients should “receive care based on the best available scientific knowledge” and that “care should not vary illogically from clinician to clinician;”

3. The need for transparency, which states that information should be made available to patients that allows them to make an informed decision when choosing among alternative health care choices.¹⁹

EVIDENCE OF EFFECTIVENESS OF SDM AND DECISION AIDS

Numerous studies have found that using patient decision aids:

- improves knowledge of health care choices,
- increases the proportion of patients with realistic perceptions of benefits and harms,
- lowers decisional conflict,
- reduces the number of patients passively involved in decision making,
- reduces the number of patients undecided after counseling, and
- improves agreement between patient values and the health care option chosen.²⁰

In a recent review of decision aid studies, the majority of studies found either improvements or no change in satisfaction with the decision, the decision-making process, and/or outcomes.²¹ SDM also reduced the rate at which patients chose more invasive surgical options. Though the rate varies from study to study, SDM reduces the uptake of invasive surgical options in favor of more conservative measures by 20 percent.²² There was also reduced choice of PSA screening and menopausal hormones.²³

There have been a few studies that examine the effect of decision aids on costs, resource use, or persistence with the chosen health care option, though more research is needed in this area. One trial compared the cost of usual care, a patient decision aid alone, and a patient decision aid followed by decision coaching to elicit patient preferences. The cost analysis, based on patient-reported resource use data, found that a decision aid, either used alone or with nurse coaching, had lower mean costs (\$2,026 and \$1,566 respectively), compared to usual care (\$2,751).²⁴

Shared decision making is also quite effective for end of life and advanced illness care planning decisions. One study found that video decision aids depicting advanced dementia improved decision making by decreasing uncertainty regarding the patients' preferences, especially for patients with limited health literacy.²⁵ A separate study found that older patients who viewed a video depicting a patient with advanced dementia were more likely to prefer comfort care, and also had more stable preferences over time and maintained their initial decision of preferring comfort care. The majority (88 percent) of patients found the tool "very helpful" or "somewhat helpful", 85 percent were "very comfortable" or "somewhat comfortable" viewing the video, and 95 percent of patients said they would "definitely" or "probably" recommend the video to others.²⁶

SHARED DECISION MAKING IN FEDERAL LEGISLATION AND REGULATIONS

There is momentum to advance SDM nationally, especially in alignment with health reform initiatives. The Affordable Care Act (ACA) establishes SDM as a priority and supports future work in this area.

Section 3506 of the ACA provides for the establishment of independent standards for certification of patient decision aids; for the development, update, and production of patient decision aids to assist providers in educating patients; and grants to support implementation. The ACA also amends the Public Health Services Act to develop a quality measure that includes the use of SDM and preference sensitive care. However, no funding has been appropriated for section 3506.

SDM is also promoted in section 3021 as one of 18 payment and service delivery models the Center for Medicare and Medicaid Innovation (CMMI) will test. The SDM model identified includes assisting applicable individuals in making informed health care choices by paying providers of services and suppliers for using patient decision-support tools that improve individual and caregiver understanding of medical treatment options. Funding has been appropriated for this section. In addition, a \$1 billion Health Care Innovation Challenge funding opportunity was recently released by CMMI to test models for system transformation, including SDM, and received an enthusiastic response, although states are not eligible to apply.

Shared decision making is also featured in the final regulations for ACOs submitted by the Center for Medicaid and Medicare Services. The regulations recommend that ACOs embrace goals that honor individual preferences and engage patients in SDM regarding diagnostic and therapeutic options.²⁷ Proposed ACOs must describe how they intend to communicate clinical knowledge/evidence-based medicine to beneficiaries, and also how they will address beneficiary engagement and SDM.²⁸ The final regulations also include a shared decision making question in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey in the measures establishing quality performance standards that ACOs must meet for shared savings.²⁹

STATE STRATEGIES TO IMPLEMENT SHARED DECISION MAKING

States that have implemented or considered implementing SDM have used a variety of approaches in order to incorporate SDM into state policy, often using more than one approach concurrently. States have multiple points of leverage to promote SDM, such as incorporation into existing quality improvement strategies or through state legislation. They can use their leverage as independent purchasers and regulators of care or partner with private payers and purchasers. States can also plan and support pilot and demonstration projects with local providers and hospitals to inform broader statewide implementation of SDM.

The states profiled below used similar overall strategies to implement SDM, but used different points of leverage depending on their individual circumstances. States with SDM champions and established broader quality initiatives enacted legislation that then set the stage for demonstration projects; other states are developing pilots through public-private partnerships they hope will provide the experience needed for eventual legislation or broader statewide adoption of SDM. This section divides these strategies into four broad approaches: legislation, pilots, public-private partnerships, and incorporation into state standards and expectations. Most states have combined these approaches, though they use them differently. The companion document, “State Legislative and Regulatory Approaches to Shared Decision Making,” provides legislative and regulatory language for the state approaches that are described in this report.

STATE EXPERIENCE WITH SHARED DECISION MAKING

Many states have taken steps to implement SDM through a variety of policy strategies, including legislation, public-private partnerships and collaborations, and incorporation into state standards and expectations (e.g. medical home or ACOs). Although many of these states are in the early stages of implementation, important lessons are already evident from their experiences. Table 1 provides an overview of leading states’ approaches to SDM; these approaches are discussed in more detail following the table.

TABLE 1: LEADING STATES’ APPROACHES TO SDM

State	Approach		
	Legislation	Public-Private Partnerships	Incorporation into State Standards and Expectations
Maine	<ul style="list-style-type: none"> ▪ 2009 legislation required formation of stakeholder group to determine implementation plan. ▪ 2009 legislation required final report to legislature on findings and recommendations. 	<ul style="list-style-type: none"> ▪ Stakeholder group created under Maine Quality Forum reviewed SDM to create final report to legislature. ▪ SDM discussed in steering groups for incorporation into ACO standards. 	<ul style="list-style-type: none"> ▪ Planning to integrate SDM into ACO models that will provide care through the state employee health plan. ▪ Incorporated SDM into guidelines on informed consent by Maine Board of Licensure in Medicine.

State	Approach		
	Legislation	Public-Private Partnerships	Incorporation into State Standards and Expectations
Minnesota	<ul style="list-style-type: none"> 2011 legislation considered that would have mandated providers engage in SDM for a list of preference-sensitive conditions performed in non-emergency situations, and certify the patient participated in SDM prior to receiving authorization or reimbursement. 	<ul style="list-style-type: none"> Minnesota Shared Decision Making Collaborative – composed of providers, patients, health plan representatives, state officials, medical association representatives, and others – was formed in 2008. Goals: identifying best practices for providing and implementing SDM, implementing best practices in MN, and reducing unwarranted variation in preference-sensitive care. 	<ul style="list-style-type: none"> Incorporated SDM into its health care home certification standards (2010). Required plans to ensure patients have an opportunity to engage in SDM in order to be recertified as a health care home at the end of their first year.
Oregon	<ul style="list-style-type: none"> May be incorporated in legislation in 2012. 	<ul style="list-style-type: none"> Discussing SDM in the Oregon Health Policy Board health transformation work groups that are providing input on initiatives that are part of Oregon’s broader health reform efforts. 	<ul style="list-style-type: none"> Oregon Public Employees and Educators Benefits Boards included SDM as patient education following a shift to value-based insurance design (2010). Considering how to incorporate SDM into medical home standards. Considering how to implement SDM in conjunction with its recent health reform efforts to create Coordinated Care Organizations.
Vermont	<ul style="list-style-type: none"> 2009 legislation required a plan for an SDM demonstration project to be integrated with the state’s broader health reform strategy (the Vermont Blueprint for Health). 		<ul style="list-style-type: none"> Engaging providers and practices in SDM demonstration projects through facilitators assisting with Patient Centered Medical Home implementation.

State	Approach		
	Legislation	Public-Private Partnerships	Incorporation into State Standards and Expectations
Washington	<ul style="list-style-type: none"> ▪ 2007 legislation mandated an SDM demonstration project at one or more multi-specialty practice site. ▪ 2007 legislation recognized SDM in the state's law on informed consent. During a malpractice suit, patients that viewed certified patient decision aids must establish a higher standard of proof that they did not provide informed consent for their health care choice. ▪ 2011 legislation designated SDM as one strategy to be used by a governor-appointed collaborative to improve health care quality, cost-effectiveness, and outcomes through state purchasing requirements. ▪ 2012 proposed legislation to establish a certification process for decision aids. 	<ul style="list-style-type: none"> ▪ Formed a Shared Decision Making/Patient Decision Aid Collaborative following the 2007 legislation. 	

LEGISLATION

Three states (Maine, Vermont, Washington) have enacted legislation related to SDM, and other states have considered or are in the process of drafting legislation.

Washington State has the broadest reaching legislation related to SDM. A bill enacted in 2007 mandated that the Health Care Authority, Washington's health care state agency, implement a SDM demonstration project at one or more multi-specialty practice sites, and recognized SDM in the state's law on informed consent by establishing SDM and use of certified patient decision aids as prima facie evidence of patients' informed consent.³⁰ As a result, patients that participate in SDM and then proceed with a particular health care choice have a much higher standard of proof in showing they did not provide informed consent for their choice. This provides more legal protection for physicians who engage in SDM with their patients with certified decision aids, but since there is no current certification process, this protection has not yet taken effect.³¹ However, the legislation also specifies that failure to engage in SDM will not be deemed admissible as evidence of failure to obtain informed consent.

The purpose of this law is to "promote public-private collaborative efforts to broaden the development, certification, use, and evaluation of effective decision aids and by recognition of SDM and patient deci-

sion aids in the state's laws on informed consent."³² In addition to the 2007 bill, a 2011 bill called for the governor to appoint a collaborative to improve health care quality, cost-effectiveness, and outcomes. SDM is identified as one strategy for the collaborative to increase the use of evidence-based standards, or to promote improved care outcomes for a health care service that lacks evidence-based best practices.³³

Washington state legislators also proposed legislation in early 2012 to establish a certification process for decision aids. Though not final, this legislation would establish a certification process by ensuring decision aids meet the International Patient Decision Aid Standards (IPDAS).³⁴

Maine and Vermont have also laid the groundwork for SDM demonstration projects and studies. Maine legislation required the Maine Quality Forum to "convene an advisory group of stakeholders to develop a plan for implementation of SDM as a strategy for improving the quality of medical care and for controlling the unnecessary use of preference-sensitive health care services," and to submit a final report to the legislature on findings and recommendations.³⁵ The report recommended a demonstration project to address issues that are critical to the advancement and spread of SDM in Maine, including:

- identifying the cost of implementing SDM;
- designing mechanisms to track short- and long-term patient outcomes;
- determining the feasibility, effectiveness, and efficiency of embedding SDM into the provision of health care;
- identifying appropriate patients;
- identifying strategies for engaging patients in SDM; and
- assessing the use of non-physician personnel and technology in SDM.³⁶

Vermont's legislation, enacted in 2009, requested a plan for an SDM demonstration project to be integrated into the state's broader health reform strategy (the Vermont Blueprint for Health). The project plans to analyze potential barriers to health care professionals participating in SDM, including existing law on informed consent, and would recommend solutions or incentives to encourage participation by health care professionals in the demonstration project.³⁷

Legislation was debated in Minnesota in 2011 that would have mandated that providers engage in SDM for specific preference-sensitive conditions performed in non-emergency situations. This legislation would have required a health care provider certify the patient participated in SDM prior to receiving authorization or reimbursement. This legislation failed due to concerns from the provider community and from the Minnesota SDM collaborative about mandating SDM before there had been adequate experience with it in practice in the state.

PILOTS

One common factor in state legislation is the establishment of pilots and demonstration projects to evaluate SDM's effectiveness in achieving patient satisfaction goals, its impact on patient understanding of health care options, and its effect on health care utilization.

The pilot study conducted by Group Health Cooperative in Washington State is the most comprehensive deployment and evaluation of SDM conducted to date in the United States. Washington state health officials partnered with Group Health in the development and implementation of legislation that mandated a multi-specialty demonstration project. Group Health leadership wanted to engage its own integrated

group practice in quality improvement efforts with an emphasis on reducing variation, improving quality, and reducing costs, and also wished to spur similar efforts throughout the community.

Group Health began its shared decision making initiative by targeting conditions for SDM interventions. They evaluated areas of high variation through the non-Medicare hospitalization Dartmouth Atlas analysis for Washington, as well as state variation data and analyses compiled by Washington State's Office of Financial Management. They then evaluated variation within Group Health itself and determined which video decision aids were available for the highest variation conditions.

Group Health focused initial implementation of SDM in a variety of specialty areas, rather than primary care, for several reasons. At the time, Group Health's primary care practices were already engaged in a full-scale roll-out of a comprehensive medical home initiative. Additionally, assuring specialists were engaged and felt ownership of the initiative was considered critical to its long-term success. They also felt certain conditions, such as cardiac care and cancer care, necessitated direct specialty provider engagement in order to have effective SDM. Given the variation in workflows at each specialty clinic, the research staff at Group Health worked with each of the specialty service lines to identify the workflow for each health condition and determine the best timing and method for incorporating SDM. They distributed decision aids prior to the initial visit if possible, though workflow and condition variations necessitated that some decision aids be distributed following the initial visit. This was especially true for conditions that were undiagnosed at the time the appointment was created.

Group Health trained physicians and their staffs throughout the implementation process, including through mandatory continuing medical education events where staff learned how to have SDM conversations and make use of the decision aids. The CME events were well received and deemed a worthy investment of time by leadership.

Group Health coupled its SDM initiative with a large scale and comprehensive evaluation designed to inform future implementation improvements and determine the impact of SDM on overall cost of care, procedure rates, and patient and provider response. The first stage of measurement used patient satisfaction surveys to assess how patients viewed the decision aids and how useful they found the information, whether they would recommend the decision aids to others, and whether they wanted decision aids for other conditions. Results from the patient satisfaction survey were very positive and Group Health distributed the patient satisfaction information to providers to demonstrate patients valued the SDM process. This feedback provided additional motivation to providers who were uncertain about the value of SDM. Additionally, the leaders of the pilot project tracked the number of decision aids distributed so providers could have feedback about their distribution rates over time and make adjustments.

The second round of measurement focused on the defect rate, which is the number of interventions that occurred without the patient first viewing a decision aid. Tracking the defect rate allowed Group Health to measure and improve the distribution rate for the aids. They also analyzed cost and utilization data for the various conditions. After reviewing the results of the pilot, Group Health decided to continue and broaden deployment of SDM across the organization and its network of contracted providers.

Other states are in the process of designing demonstration projects. Since publishing the report on SDM, Maine's Dirigo Health, through the Maine Quality Forum, is planning a pilot focused on how purchasers, working with primary and specialty practices, can advance the use of SDM. The pilot aims to:

- create and operationalize a working definition of SDM, to be used by providers and payers for payment, program recognition, and quality measurement;
- identify core metrics for documenting SDM and its efficacy;

- develop a payment model;
- develop and test incentives for providers and patients to participate in SDM;
- determine the factors required for successful implementation and payment, and;
- evaluate the impact of SDM on the cost and quality of care.

PUBLIC-PRIVATE PARTNERSHIPS

Several states have established public-private partnerships or steering committees to determine how to best implement SDM and involve stakeholders in implementation. Some states are using public-private partnerships and workgroups established for broader health reform, whereas other states have partnerships exclusively focused on SDM.

The Minnesota Shared Decision Making Collaborative—composed of providers, patients, health plan representatives, state officials, medical association representatives, and others—was formed in 2008. A charter document established goals such as identifying best practices for providing and implementing SDM, implementing best practices in MN, and reducing unwarranted variation in preference-sensitive care.³⁸ Members have found this collaborative to be useful for aligning policy goals among collaborative members, sharing expertise among members, and connecting members to lobbying efforts for SDM.

Washington State also formed a Shared Decision Making/Patient Decision Aid Collaborative following 2007 legislation. The purpose was to identify, coordinate, and share activities and resources; develop criteria and a framework for WA's legislative demonstration project; provide demonstration site support; exchange information and develop partnerships; reduce duplicative efforts; and provide expertise, best practices, samples, and resources. The collaborative also developed criteria and a framework for Washington's demonstration project. This collaborative was composed of representatives from the Washington State Health Care Authority, the University of Washington, Group Health Cooperative, and other providers, individuals, insurers, and health policy organizations.³⁹

Washington State's 2011 legislation also created the Bree Collaborative, which consists of 20 members appointed by the governor, ranging from health plan representatives, providers, purchasers, and state officials. The Collaborative must annually identify three health care services showing "substantial variations in practice patterns or high utilization trends" in Washington, and "identify evidence-based best practices to improve quality and reduce variation in the use of service," for which SDM is a designated strategy. All state-purchased health care services must implement the evidence-based practice guidelines and strategies each year.⁴⁰

Oregon is discussing SDM in the Oregon Health Policy Board health transformation work groups that are providing input on initiatives as part of Oregon's broader health reform efforts. These workgroups will discuss how to implement SDM in alignment with these reforms, and will seek legislative approval in 2012. The workgroups are composed of the Oregon Health Authority staff, providers, advocates, health plan representatives, and other communities across the state.

Maine is similarly discussing SDM in steering committees being developed to determine ACO standards, and in a workgroup that is designing the pilot for Dirigo Health.

INTEGRATION INTO STATE STANDARDS AND EXPECTATIONS

Most states examined in this project are integrating SDM into their delivery system reform efforts through standards for Medical Home or ACO certification. The reasons for this strategy are two-fold: the natural

fit of SDM in initiatives focused on patient engagement and patient-centered care, and as a means of easing the challenges of implementing SDM independently.

Vermont is in the process of certifying every primary care practice in the state as a Patient Centered Medical Home (PCMH) by 2013. The Blueprint for Health launched the Expansion and Quality Improvement Program (EQulP) to provide guidance and support to primary care practices through the process, and has teams of facilitators working with practices to assist them with the transformation.⁴¹ After receiving pushback on the initial SDM demonstration project proposal from some provider groups, the state has adopted the approach of using the EQulP teams to engage provider practices in pursuing SDM pilots in conjunction with their transition to a PCMH. The goal is to engage providers through effective facilitators with whom they already work, thus reducing the challenges associated with independently implementing SDM.

Minnesota has incorporated SDM into its health care home certification standards. SDM is incorporated in the definition of patient and family-centered care, which states that health care should be planned, delivered, and evaluated “through patient-driven shared decision-making that is based on participation, cooperation, trust, and respect of participant perspectives and choices” that incorporate the “participant’s knowledge, values, beliefs, and cultural background into care planning and delivery.”⁴² Plans must also ensure patients have an opportunity to engage in SDM in order to be recertified as a health care home at the end of their first year. Minnesota state officials felt it was important that SDM to be aligned with a broader system redesign model, and that SDM be used as a tool for strengthening the patient centered principle within the health care home model. Minnesota also cited similar reasons as Vermont in their desire to encourage providers to participate rather than adding a separate SDM-specific project.

Minnesota officials have defined SDM more broadly so that it applies to situations beyond those normally considered preference-sensitive, and so that SDM can occur with or without a decision aid. They prefer the expanded definition to emphasize that the goal of SDM is to help patients have the right information at the right time so they may make choices and participate as partners in decision making.

According to state officials in Maine, SDM will be integrated into new ACO models being developed in projects with health care centers that provide care contracted through the state employee health plan. SDM is on a mutually agreed-upon list of fundamental principles and concepts that the state and health care centers want to include in the ACO model. Some logistical issues remain as to whether primary care providers or specialists would engage the patient in SDM, and how providers would be reimbursed through the third party administrator. The state also plans to integrate SDM into quality goals for its health insurance exchange.

In addition, the Maine Board of Licensure in Medicine released guidelines that encourage physicians to use SDM during the process of obtaining informed consent, the first in the country to do so. These guidelines were issued due to a significant number of complaints from patients of communication issues with their physicians involving informed consent. This document includes a definition of SDM and specific recommendations of skills for eliciting informed consent, such as empathetic listening, disclosing, explaining, and framing. The board recommended Maine physicians adopt and apply a definition of informed consent that includes disclosing and explaining the process used to arrive at the medically reasonable and recommended intervention to the patient’s satisfaction, and that physicians give patients ample opportunity to ask questions about the process and the recommended intervention(s).⁴³

The Oregon Health Policy Authority is actively considering how to incorporate SDM into medical home standards, and is also considering how to implement SDM in conjunction with its recent health reform

efforts to create Coordinated Care Organizations, community-based networks of providers charged with providing coordinated patient-centered care. Discussions are underway to determine details of implementation and whether SDM will be mandatory or simply encouraged. The Oregon Health Authority views SDM as a good fit in these initiatives since it can help improve quality and help reduce unwarranted utilization and control costs.

Oregon has recently implemented value-based insurance design through the Public Employees and Educators Benefit Boards for its state employee and public educator health plans and uses SDM as a patient education tool in conjunction with the insurance redesign. The redesigned plans increase copayments for preference-sensitive services of low relative value, and cover preventive and high-value services at low or no cost.⁴⁴ The additional cost tier requires a co-payment not subject to the deductible or out-of-pocket maximums for specific types of care, including: emergency room visits; arthroscopy; hip and knee replacement; magnetic resonance imaging, computed tomography, and positron emission tomography scans; upper endoscopy; gastric bypass surgery; and spinal surgery. Cancer treatments are exempt from the higher cost share.⁴⁵ The benefit boards believe this approach is effective because it enables patients to cite additional costs as a consideration when discussing health care options with their providers.

Oregon implemented SDM as member education for its state employee health plan in conjunction with the value-based insurance design. The benefit boards felt it was important to provide more information about the procedures that required a higher copayment. The website that explains the insurance plan links to the insurance carrier's website for decision support materials. Additionally, one carrier implemented a program that allowed primary care physicians to write an "information prescription" for four major care conditions (low back pain, large joint pain, stable angina, cancer screening) that would email a decision support tool to the patient, and that patient's answers would be emailed back to the physician. The physicians were rewarded a \$100 incentive for each completed decision support tool, and the patients were given a non-cash \$15 reward.

BARRIERS AND SOLUTIONS FOR IMPLEMENTATION

While SDM has a strong evidence base supporting its role in quality improvement, states note they have run into challenges with implementing SDM due to process ambiguities, certification issues with decision aids, provider reimbursement and engagement, and other stakeholder concerns. The meeting explored some of these barriers and potential solutions.

DEFINITION OF SHARED DECISION MAKING AND INTEGRATION INTO THE CARE PROCESS

Some states mentioned they have found the absence of a formal working definition of SDM to be challenging when considering how to implement or include it in legislation or regulations. Although prior literature found there has been little coherence in a working definition of SDM,⁴⁶ many organizations have since documented the process they use for SDM,⁴⁷ and specific definitions are present in the Affordable Care Act and Washington State legislation. In addition, the process undertaken to incorporate SDM differs by care setting (hospital, clinic, surgery center) and the procedures for which it is used (screening, surgical procedures, chronic disease management). Thus, states and provider organizations must consider how to incorporate SDM on the basis of their particular circumstances, creating an additional perceived barrier to implementation.

States face a challenge to clearly define SDM in order to set expectations. If providers or plans are to be held accountable for implementing SDM, there need to be clear guidelines and methods for measuring implementation. A specific definition of SDM is also necessary to help distinguish it from informed consent; while SDM could be considered the gold standard of informed consent, informed consent in and of itself does not constitute shared decision making.

Defining SDM also helps clarify how to integrate it into the care process with regard to whether patients will receive decision aids prior to speaking with their provider, if at all, and which providers will be involved in the SDM process. Meeting participants discussed different approaches to integrating SDM into the care process depending on the setting of care and goals of the organization (i.e., broad scale implementation and culture change, or a small test of change). Most meeting participants recommended starting with only a few conditions and ensuring that the patients view a decision aid prior to meeting with the specialist provider, though some decision aids are meant to be used in conjunction with a consultation. This usually requires working closely in the clinic setting to determine the initial point of contact with the patient, and the patient's condition must be identified prior to their initial visit with the specialist.

Electronic medical records can be of great assistance in reminding the provider to give the patient a decision aid and engage in a SDM conversation. They can identify patients who will be facing a decision, such as those who are eligible for a mammogram or screening for colon cancer. The electronic medical record can notify the provider of a relevant decision aid once certain diagnosis codes are entered, and directly mail the patient a copy of the decision aid.⁴⁸

CERTIFICATION OF DECISION AIDS

States cite the lack of certification for patient decision aids as one of the greatest barriers to implementation. Though the International Patient Decision Aid Standards (IPDAS) Collaboration has created a checklist for agreed-upon standards for high quality decision aids, there is no current national body responsible for certifying that decision aids adhere to this checklist.⁴⁹ This poses challenges to policymakers in implementation and may also reduce provider and public confidence. Certification helps providers, patients, and payers evaluate the quality of decision aids, mitigates financial risk to payers, and is needed to ensure that decision aids are unbiased, comprehensive, accurate, and as up-to-date as possible.⁵⁰ The

lack of a national organization that creates and certifies decision aids requires states to choose among different companies and products, leading to less consistency. Decision aid developers also require resources to create and keep aids timely and accurate, and states note it is difficult to afford these costs outside of research-funded pilots.

States cite certification as a major barrier due to the cost of undertaking a certification process on the state level and the hesitation of providers to support SDM without certified decision aids. Guidelines for certification requirements and suggested processes have recently been proposed, but there is not yet any funding for this effort.⁵¹ Some demonstration projects, such as Group Health's multi-specialty pilot, have been able to successfully implement SDM without certified decision aids, but all meeting participants cited a preference for certified decision aids. In the meantime, organizations can request an International Patient Decision Aids Standard Instrument (IPDASi) assessment to evaluate decision aids for the criteria developed by the IPDAS collaboration.⁵² A list of decision aids with a completed IPDAS checklist assessment is available on the Ottawa Hospital Research Institute website.⁵³ Proposed legislation in Washington state would establish a certification process for decision aids used in the state by ensuring they meet IPDAS criteria.⁵⁴

REIMBURSEMENT OF PROVIDERS

States have struggled with determining whether to reimburse providers for participating in SDM with their patients or if SDM should be part of routine care that is not reimbursed separately. States have also given significant consideration to which provider should engage the patient in SDM; whether it is more appropriate for a specialist or the primary care physician, or whether a nurse or care navigator should primarily engage the patient. The main considerations states have when determining whether to reimburse providers is the length of time required to participate in SDM and the use of reimbursement as an incentive for provider participation in SDM. Studies of the effect of SDM on consultation length have had mixed results, showing both increases and decreases in consultation length after patients have viewed a decision aid.⁵⁵ The change was primarily dependent on the condition being discussed.⁵⁶ Even if they choose not to reimburse providers, states have struggled with how to supply hospitals or other care settings with sufficient resources to incorporate SDM into the care process, such as the money to cover the costs of decision aids or education campaigns for patients and providers.

States that have implemented SDM have used varied strategies for provider reimbursement. Some states, such as Washington, do not separately reimburse providers for engaging in SDM. In the Group Health pilot, physicians were expected to engage in SDM for a predetermined set of conditions, regardless of whether they were salaried or network providers. Other states, such as Maine, investigated codes for evaluation and consultation that providers can use when they conduct SDM in order to incentivize and reward providers. States that are implementing SDM in conjunction with Patient Centered Medical Home initiatives tend to link SDM to a list of medical home activities required for incentive payments.⁵⁷

States also vary as to whether they view primary care or specialty care as the appropriate setting for SDM. The states and demonstration projects that have reimbursed providers tend to view primary care as the preferred setting for SDM. They believe that specialists will have a financial bias against engaging in SDM, since patients often choose less invasive procedures after SDM. Alternatively, the Washington pilot at Group Health engaged specialists in SDM since they felt that certain conditions, such as cancer and cardiac care, were best discussed by specialists with experience in those treatments. They also felt engaging the specialists first was important to obtain buy-in, since SDM would ultimately impact the care they provide.

Most meeting participants believed SDM could be conducted by physician and non-physician providers, such as nurse practitioners, nurses, and other providers in decision coaching roles. The Group Health pilot engaged every provider in the care setting to implement SDM, including medical assistants and nurses. Furthermore, there are validated inter-professional provider models for implementation of SDM.⁵⁸

PROVIDER RESISTANCE

Provider resistance to implementing SDM arises from concern about how it will fit into the patient care workflow and the appropriateness of patient decision aids for the provider's patient population. Structural barriers cited include time pressure and lack of applicability due to the patient characteristics or clinical situation.⁵⁹ Additionally, providers in a fee-for-service environment may have a financial disincentive to participate in SDM if it reduces the use of high-cost procedures. The use of patient decision aids is facilitated by the perception that SDM will lead to a positive impact on patient outcomes and the clinical process. Engaging providers to inform them about the SDM process, patient decision aid tools, and the benefits and drawbacks would be crucial in any successful implementation plan.

States with SDM experience cited some provider resistance for similar reasons, especially time pressure and burnout from quality improvement initiatives. Group Health also noted provider resistance and uptake of SDM was often dependent on the specialty. Providers were more enthusiastic about SDM for elective, non-life threatening procedures such as knee and hip replacement, but resistant in areas such as cardiac care, since the associated conditions were viewed as more immediately life threatening. Provider uptake also depended on the providers' own perceptions and work style.

Effective strategies for provider engagement and obtaining provider buy-in have included strong leadership to encourage SDM implementation for all providers, and emphasizing that SDM leads to better informed patients and improves patient care. Providers were less amenable to SDM when the emphasis was placed on cost reduction and unwarranted variation. One review study found that providing health care professionals with educational meetings, materials, and feedback improved adoption of SDM.⁶⁰

MEASUREMENT AND METRICS

Determining how to measure the success of SDM and its impact on patient satisfaction, quality, and utilization has been of concern to states. Individual provider organizations have often created their own quality measurement metrics, frequently relying on the use of patient and provider satisfaction surveys. In addition, they can measure the effect of SDM on utilization of specified procedures. However, there is only one national measure on the CAHPS survey regarding patient satisfaction that includes SDM. A three-question set is used to assess patient-centered care in the supplemental item set of the health plan survey for children with chronic conditions, and a four-question set is used in the patient-centered medical home survey.^{61, 62} The lack of a standard working definition also impedes accurate measurement and comparison, especially across different organizations that may be using SDM for different procedures and using varied patient decision aids, making it difficult to differentiate which components of the process are essential or have the most impact.

States and stakeholders suggested there were many different ways to measure the success of SDM, and the measurement goals primarily determined the best approach. Identifying the correct indicator for SDM depends on whether the goal is to evaluate the organization, provider, or patient, and similarly whether the goal is to assess the structure, process, or outcome. Success also depends on whether the goal is measurement for quality improvement purposes or for accountability. For example, to measure outcomes on the organizational level, the percentage of patients receiving decision aids and the result on utilization rates could be evaluated. However, an evaluation of decision quality and patient satisfaction would be more appropriate for measuring outcomes for pa-

tients. There are also structure and process measurements that can assist in improving implementation of SDM – such as assessing the presence of SDM summaries in the health record, and the frequency with which individual providers distribute decision aids.

Despite measurement challenges, meeting participants noted the need to keep moving forward, and that imperfect measurement is preferable to waiting for perfect measures. Nationally, NCQA is identifying structure and process measures to operationalize measurement of SDM for both patient-centered medical homes and ACOs.

MEDICAL MALPRACTICE

Another challenge of concern to states is medical malpractice. Some providers are concerned that patients may be more likely to sue if they choose not to have procedures or screening through SDM but develop a more serious condition later.⁶³ In addition, some providers have pushed back against some state efforts to change the definition of informed consent to include SDM.

Meeting discussion and research literature indicate that concerns about medical malpractice were less common among providers than concerns about time constraints and applicability of SDM to clinical situations. One study found that using a decision aid in conjunction with SDM offered protection for physicians against a malpractice ruling in a mock trial.⁶⁴ Focus groups representing potential jurors were presented with a case where a man sued after being diagnosed with prostate cancer following an earlier decision not to obtain a Prostate Specific Antigen (PSA) test due to his physician's advice. When potential jurors in focus groups were told the physician showed the patient a video decision aid for a PSA test, 94 percent felt the standard of care had been met and only 4 percent felt harm had been caused. This offered significant protection compared to only a note in the medical record, where 72 percent of potential jurors felt the standard of care had been met and 23 percent felt harm had been caused.⁶⁵

ACA AND FEDERAL IMPLEMENTATION

Federal implementation of section 3506 in the Affordable Care Act (ACA)—which calls for the establishment of independent standards for certification of patient decision aids and the development of patient decision aids—has not progressed due to lack of appropriated funding. However, states can leverage other opportunities in the ACA to promote SDM. States have to certify health plans in order for them to be offered in health insurance exchanges, and can choose to be “active purchasers” and set additional certification criteria that reflect goals for quality and delivery system reform.⁶⁶ If states choose the active purchasing approach, they could require plans offered in exchanges to provide an online portal for decision aids or encourage their providers to engage in SDM.

There is also federal activity in this area beyond the ACA. The Effective Health Care Program at the Agency for Healthcare Research and Quality distributes patient decision aids, and has some funding available for the creation of future decision aids.

Though federal assistance for state implementation of SDM is limited, states can apply for funding through the Patient Centered Outcome Research Institute (PCORI). PCORI’s mission—to conduct research to “provide information about the best available evidence to help patients and their health care providers make more informed decisions”—is closely aligned with the goals of SDM.⁶⁷ Though funding opportunities are only available for limited periods of time, there are often grant opportunities for pilot projects that state governments and organizations could conduct.

The Center for Medicare and Medicaid Innovation recently released the Health Care Innovation Challenge funding opportunity to identify models that “accelerate system transformation towards better care, better health and lower costs through improvement.”⁶⁸ Though states or state agencies are not eligible, the grant opportunity was open to providers, payers, local government, public-private partnerships and multi-payer collaboratives.⁶⁹ Shared decision making systems are listed as a specific model of infrastructure funding that could be supported by the Challenge; grant applications were due in late January 2012.⁷⁰

As noted previously, states indicate that the area of greatest assistance needed from the federal government is in financing and creation of a certification process, as detailed in the Affordable Care Act.

RECOMMENDATIONS FOR STATES TO ADVANCE SHARED DECISION MAKING

Several recommendations have emerged from state experiences to date in implementing SDM:

- **Build SDM into current momentum to transform the health care delivery system.** It is important to place SDM in a context of improvement by integrating it into existing priorities and quality goals, such as medical homes, ACO requirements, or value-based purchasing. This helps reduce the burden of independent implementation and helps integrate the change into the overall change providers are facing in the health care system. States can review current quality initiatives and explore whether the initiatives incorporate SDM as a way of integrating SDM into the culture and expectation of quality improvement.
- **Capitalize on state roles as purchasers, regulators, conveners, and educators.** Though numerous strategies are available to states to leverage their role as a purchaser, they may find they have difficulty using Medicaid payments as leverage over providers given the low payment rates. In addition, states will have to be specific about the requirements of their request when mandating participation in SDM to avoid plans or providers merely checking a box on a report. Exchanges are the greatest future opportunity for states to leverage their role as a purchaser, and states can consider whether they have the ability and opportunity to be an active purchaser and influence the inclusion of SDM in the plans available in the exchange.⁷¹

TABLE 2. STATE OPTIONS TO ADVANCE SDM

Purchasing Strategies
<ul style="list-style-type: none"> • Leverage role as a purchaser and payer to include incentives to use SDM in state contracts with health plans for state employees, Medicaid patients, and in the exchange. • Give preference to health plans demonstrating use of SDM during state procurement process or through auto-assignment of beneficiaries. • Require provider or plan reporting of patient experience using surveys that incorporate questions relating to SDM. • Use active purchasing to require plans in the exchange to provide decision aids on the Web. • Adopt pay-for-performance incentives that encourage providers to incorporate SDM into their practices. • Encourage SDM as an optional performance improvement project to meet requirements for contracted health plans.⁷² • Authorize an entity (such as WA's Bree Collaborative) to identify health care services with high variations along with best practices for reducing variation. • Designate SDM as one of the evidence-based practice guidelines and strategies that state-purchased health care services must incorporate to reduce the variation.
Regulatory Strategies
<ul style="list-style-type: none"> • Provide guidelines about using SDM through state licensure boards. • Amend state clinician licensure laws to require demonstrating SDM proficiency as a condition of maintenance of licensure.

Convening, Educating, and Partnership Strategies

- Select SDM as a “focus topic” for statewide quality improvement initiatives.
 - Participate and convene public-private partnerships to advance SDM.
 - Design pilot projects to test implementation strategies.
 - Encourage state clinical training programs to incorporate SDM training and education into their curricula.
 - Fund the development and maintenance of decision aids, or provide access to decision aids.
-
- **Use a multi-faceted approach in collaboration with private partners.** Public-private partnerships can be an effective vehicle for implementing SDM by influencing stakeholder buy-in and providing resources and knowledge to conduct demonstration projects. It is important for these partnerships to be inclusive of both state government and private partners. Private health plans that have a large state presence may be willing partners in this effort and a financial resource to assist in implementation.
 - **Engage providers as partners throughout the SDM process; providing adequate training, and using provider expertise to integrate SDM into the care process is critical.** Providers may initially be resistant to SDM due to the perception of time constraints and concerns about the value of SDM to their patient population, but they are often the biggest proponents once the supporting data on patient satisfaction and decision quality is evident. Without provider support, SDM may just become another check box on a form rather than an actual process of patient engagement.
 - **Implement SDM in an integrated system if available; if not, implement in a fee-for-service system.** SDM is most doable in an integrated system where there are aligned financial incentives to improve patient care and decrease variation. Implementing SDM in a fee-for-service environment would likely necessitate a leadership-driven and funded initiative, as physicians would be unlikely to spearhead implementation given the financial disincentives involved if patients choose less invasive (and less expensive) procedures.
 - **Identify conditions with significant variation in utilization rates according to state data or state-specific Dartmouth Atlas analysis and consider state legislation to promote pilot projects that address those conditions.** States can identify decision aids that are available for these conditions and conduct a test of change.
 - **Encourage national certification of decisions aids to foster adoption.** Certification ensures decision aids are comprehensive, up-to-date, accurate, and unbiased. Providers may be hesitant to rely on uncertified decision aids as a patient education and engagement tool.

CONCLUSIONS

Shared decision making is one tool for states looking to achieve improvements in patient-centered and evidence-based care. There is unequivocal evidence that SDM improves the quality of health care decisions, but the challenge is implementing SDM successfully in a world of competing priorities. Though providers and most stakeholders are supportive of SDM, they find it challenging to determine how to move forward with implementation given the barriers, such as the cost of decision aids or how to effectively integrate SDM into the care process.

States have multiple points of leverage to draw on in their roles as purchasers, regulators, and conveners in order to implement SDM. States can implement SDM via legislation, through integration into other state strategies and public-private partnerships, incorporation into state standards and expectations, or through multiple approaches used together.

States and health systems have many choices to make when implementing SDM, including whether to focus on implementation in primary care or specialty care settings; focusing on a few state-specific conditions where there is unwarranted variation as indicated by the Dartmouth Atlas, or applying SDM more broadly; and how to integrate SDM into the care process. Though the choices are not simple, they allow states to customize SDM to their specific situations and use it in a way that best aligns with existing quality and strategic initiatives. If states capitalize on prior experience, partner with organizations with expertise, and draw on important lessons from leading states, they can maximize the use of SDM as a tool to improve the quality of their health care delivery systems and better meet patients' needs.

APPENDICES

APPENDIX A: KEY INFORMANTS

Name	Title	Organization/State
David Arterburn	Associate Investigator	Group Health Research Institute
Christine Bechtel	Vice President	National Partnership for Women and Families
Linda Berglin	State Senator	Minnesota
Leah Binder	CEO	The Leapfrog Group
Shannon Brownlee	Director	New America Foundation Health Policy Program
Eileen Cody	State Legislator	Washington State
Patrice Desvigne-Nickens	Medical Officer, Heart Failure and Arrhythmias	Division of Cardiovascular Sciences, National Institutes of Health
Maroulla Gleaton	Secretary	Maine Board of Licensure in Medicine
	Ophthalmologist	Atlee Gleaton Eye Care
Bruce Goldberg	Director	Oregon Health Authority
Matt Handley	Associate Medical Director, Quality and Informatics	Group Health Permanente
Laurie Harding	State Representative	New Hampshire
Karynlee Harrington	Executive Director	Maine Dirigo Health Agency
Leah Hole-Curry	Medical Administrator	Washington State Department of Labor and Industries
Frank Johnson	Executive Director	Maine Department of Administrative and Financial Services
Joan Kapowich	Administrator	Public Employees' Benefit Board and the Oregon Educators Benefit Board
Arthur Levin	Co-Founder and Director	Center for Medical Consumers
Sylvia Lopez	Medical Director	Oklahoma Health Care Authority
Marie Maes-Voreis	Health Care Homes Program Director	Minnesota Department of Health
	Member	Minnesota Shared Decision Making Collaborative
Karen Merrikin	Senior Health Policy Advisor	Group Health Cooperative
Ruth Mickelsen	Affiliate Faculty, Center for Bioethics	University of Minnesota
	Consultant	Informed Medical Decisions Foundation
Lawrence Morrissey	Medical Director of Quality Improvement	Stillwater Medical Group
	Chair	Minnesota Shared Decision Making Collaborative
Benjamin Moulton	Senior Legal Advisor	Informed Medical Decisions Foundation
Lee Partridge	Senior Health Policy Advisor	National Partnership for Women and Families

Name	Title	Organization/State
Rebecca Pasternik-Ikard	Deputy State Medicaid Director	Oklahoma Health Care Authority
Sarah Scholle	Vice President of Research	National Committee for Quality Assurance
Karen Sepucha	Assistant Professor	Massachusetts General Hospital
Jean Slutsky	Director, Center for Outcomes and Evidence	Agency for Healthcare Research and Quality
Dawn Stacey	Associate Professor	University of Ottawa
	Co-Char	International Patient Decision Aid Standards Group
Diane Stollenwerk	Vice President of Community Alliances	National Quality Forum
Kalahn Taylor-Clark	Director of Health Policy	National Partnership for Women and Families
Dorothy Teeter	Senior Advisor for Policy and Programs	Center for Medicare and Medicaid Innovation
Angelo Volandes	Practicing Internal Medicine Physician	Massachusetts General Hospital
	Junior Faculty Member	Harvard Medical School
Lisa Dulsky Watkins	Associate Director	Vermont Blueprint for Health

 APPENDIX B: ANNOTATED BIBLIOGRAPHY

EVIDENCE OF SDM EFFECTIVENESS

Barry, Michael J, et al., “Reactions Of Potential Jurors to a Hypothetical Malpractice Suit: Alleging Failure to Perform a Prostate-Specific Antigen Test.” *The Journal of Law, Medicine & Ethics* **36, no. 2 (January 2008): 396-402, 214.**

An article detailing a study that found using a decision aid in conjunction with shared decision making offered protection for physicians against a malpractice ruling in a mock trial. Focus groups representing potential jurors were presented with a case where a man sued after being diagnosed with prostate cancer following an earlier decision not to obtain a Prostate Specific Antigen (PSA) test due to his physician’s advice. When potential jurors in focus groups were told the physician showed the patient a video decision aid for a PSA test, 94 percent felt the standard of care had been met and only 4 percent felt harm had been caused. This offered significant protection compared to only a note in the medical record, where 72 percent of potential jurors felt the standard of care had been met and 23 percent felt harm had been caused.

El-Jawahri, Areej, et al., “Use Of Video to Facilitate End-Of-Life Discussions with Patients with Cancer: A Randomized Controlled Trial.” *Journal of Clinical Oncology* **28, no. 2 (January 10, 2010): 305-10.**

An article that describes a study that found that patients with cancer who viewed a video of various goals-of-care options in addition to a verbal description were more likely to prefer comfort measures and avoid CPR, were more knowledgeable regarding advanced care treatment options, and felt more certain about their decision compared to patients only hearing a verbal narrative. This article differs from some other studies regarding decision aids, since other uses of video decision support tools have focused on helping people make treatment or screening decisions, whereas this video was used to initiate end-of-life discussions.

Lewin Group, “Bending the Curve: Technical Documentation,” June 2008.

This document includes a cost analysis of implementing SDM for 11 procedures and estimates the savings to national health spending to be \$3.8 billion over 5 years and \$9.2 billion over ten years.

Stacey, Dawn et al. “Decision Aids for People Facing Health Treatment or Screening Decisions (Review).” *The Cochrane Library*, **no. 10 (2011).**

The most comprehensive review article that reviews the evidence of patient decision aids from numerous randomized control trials and provides a strong evidence base for the positive benefits of patient decision aids. The review found that when patients use decision aids they: a) improve their knowledge of the options; b) are helped to have more accurate expectations of possible benefits and harms; c) reach choices that are more consistent with their informed values; and d) participate more in decision making.

Wennberg, David E, et al., “A Randomized Trial of a Telephone Care-Management Strategy.” *The New England Journal of Medicine* **363, no. 13 (September 23, 2010): 1245-55.**

A review of a research study where patients were given telephone-based care management that coached patients with selected medical conditions and predicted high health care costs to instruct them about SDM, self-care, and behavioral change. This research goes beyond previous care-management studies in that it included patients at risk for a preference-sensitive condition decision in the future, and the health coaching included shared decision making and access to patient decision aids. The average monthly medical and pharmacy costs per person in the enhanced-support group were 3.6 percent lower than those in the usual-support group, largely due to a 10.1 percent reduction in annual hospital admissions.

Williams, Nyna and Chris Fleming, “Consumer and Provider Perspectives on Shared Decision Making: A Systematic Review of the Peer-Reviewed Literature” Center on Health Care Effectiveness Research, Mathematica, September 2011.

A brief summary of a systematic review of peer-reviewed literature that assesses current consumer and provider perspectives on the process. Both consumers and providers attitude towards SDM were more likely to be positive than negative, whereas engagement in somewhat more likely to be lower than higher. The authors conclude that actual engagement in SDM behavior is lagging behind attitudes toward the process, and recommend implementation of policies that support SDM.

POLICY STRATEGIES

Brownlee, Shannon, “Certifying Patient Decision Aids to Facilitate Shared Decision-Making: A Roadmap,” New America Foundation, unpublished.

Thorough article that advocates for a rigorous process for the development of patient decision aids and a trusted method of certification to ensure that patient decision aids are unbiased, comprehensive, accurate, and up-to-date as possible. Brownlee suggests a framework for establishing a certification process including three distinct steps: 1) developing a process for setting certification standards; 2) establishing the standards; and 3) developing the process for certifying PDAs. The article provides numerous recommendations and next steps for establishing a certification process.

Fowler, Floyd J, Carrie a Levin, and Karen R Sepucha. “Informing and Involving Patients to Improve the Quality of Medical Decisions.” *Health Affairs* 30, no. 4 (April 2011): 699-706.

This article describes the current issues surrounding informed patient decision making and how the use of SDM might improve informed decision making. The authors suggest using health information technology to bolster the use and simplify the implementation of SDM by using it to trigger the delivery of information and collect and store information. The authors also suggest the use of additional surveys to assess patients’ knowledge and goals. The article reviews public and private developments that could facilitate the development of tools and methods to improve patient-centered care. Finally, they review policy options for implementation of SDM.

Frosch, Dominick L. et al., “Shared Decision Making in the United States: Policy and Implementation Activity on Multiple Fronts.” *German Journal for Evidence and Quality in Health Care*, 105, no. 4 (January 2011): 305-12.

A review of the status of SDM implementation in the US, including state activity, federal activity, research funding, and implementation in clinical practice. It also includes a helpful list of organizations that are advocating SDM use in the US, professional and accreditation organization activity in SDM, and a list of current activity in the development of patient decision aids.

Krumholz, HM. “Informed Consent to Promote Patient-Centered Care.” *JAMA* 303, no. 12 (2010): 1190-1191.

A commentary article that suggests an improved informed consent form in order to improve patient-centered care and the proportion of patients that are well informed prior to a procedure. The author suggests that patients considering an elective procedure should be given a brief standardized and personalized informed consent document that provides information in five areas: risks, benefits, alternatives, experience, and cost. The purpose of this form would be to facilitate meaningful discussion with physicians.

O'Malley, Ann S. et al., "Policy Options to Encourage Patient-Physician Shared Decision Making," National Institute for Health Care Reform, September 2011 .

This brief is an overview of the basic tenets of SDM, the challenges of participating in SDM from the provider and patient perspective, and a review of opportunities to adopt SDM in health reform. It has a helpful review of numerous policy options that could be used to encourage adoption of SDM, including incorporating SDM into meaningful use criteria for electronic health records. Though these options are not state-specific, they could be applied to state policy.

Sepucha, Karen R., Floyd J. Fowler Jr., and Albert G. Mulley Jr., "Policy Support for Patient-Centered Care: The Need for Measurable Improvements in Decision Quality" *Health Affairs Suppl Vari (January 2004): VAR54-62.*

This article proposes that a new measure of decision quality be implemented in health care settings to ensure that patients receive the care they want and understand their health care decisions through measuring concordance of care given to patient preferences. The authors state that the quality of a clinical decision is the "extent to which it reflects the considered needs, values, and expressed preferences of a well-informed patient and is thus implemented." They suggest that a valid assessment of decision quality would require: 1) decision-specific knowledge, 2) values for the salient outcomes, and 3) treatments chosen. The paper provides examples where similar measures have been incorporated into care processes.

EVIDENCE OF NEED FOR SDM

Hawker, G et al., "Determining the Need for Hip and Knee Arthroplasty: The Role of Patients' Preferences," *Medical Care, Vol 39. No 3 (March 2011).*

This article demonstrates the need for SDM. In this study, patients with hip or knee arthritis were assessed for their need and willingness to undergo arthroplasty in two geographic regions with high and low use of the procedure. Patients were assessed for this clinical appropriateness for surgery, and then participated in an interview where they were told the consequences of not having surgery, alternative treatments, risks and benefits of surgery, and potential risks of surgery. Among individuals that were deemed clinically appropriate for surgery, only 14.9 percent in the high-rate area and 8.5 percent in the low-rate area responded as being definitely willing to undergo arthroplasty. The great variation between those patients who are clinically appropriate versus willing to undergo surgery suggest that patient values should be more routinely incorporated into clinical decisions.

King, Jaime S. and Benjamin Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision Making," *American Journal of Law & Medicine, 32 (2006)*

A comprehensive article that examines the current status and history of informed consent requirements and argues that states should clarify their informed consent requirements to include SDM as a prerequisite to a valid informed consent. The article reviews the challenges associated with modern informed consent practices and the ethical and legal foundations of informed consent. It also examines the clinical evidence for treatment patterns and patient information needs that suggest a weakness in the current legal standards. It then compares the effectiveness and implications of the three different standards of informed consent—physician-based, patient-based and shared medical decision-making—and analyzes the policy implications required to implement SDM.

King, Jaime S., Mark H. Eckman, and Benjamin W. Moulton, “The Potential of Shared Decision Making to Reduce Health Disparities,” *Journal of Law, Medicine, and Ethics*, **39 Suppl 1 (March 2011): 30-3.** An article that explores evidence that SDM can help reduce health disparities by improving patient activation and health outcomes, even for patients with lower health literacy. The authors suggest this is an imperative since previous research shows that despite lower knowledge scores, patients with less education and income felt extremely well informed with respect to medication and screening decisions.

Moulton, Benjamin and Jaime S. King, “Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice,” *Journal of Law, Medicine, and Ethics*, **38, no. 1 (January 2010): 85-97.**

This largely theoretical article describes balance between two medical decision making principles – beneficence and autonomy – and the growing shift towards a model of an autonomous, informed, and participatory patient. The article proposes that SDM strikes a balance between beneficence and autonomy and thus should be adopted more widely. Reviews policy options for implanting SDM more widely through practice models, state policy incentives, and federal requirements. The article provides some detailed examples from health systems and states that have implemented SDM through the above models, and proposes a three-step process for implementing a nationwide practice of SDM.

Stefanek, Michael E. “Uninformed Compliance or Informed Choice? A Needed Shift in Our Approach to Cancer Screening,” *Journal of the National Cancer Institute*, **November 2011**

A commentary article that criticizes the current practice in health care to conduct cancer screening without first informing patients about the benefits and harms of screening tests. Stefanek believes the lack of transparent presentation of data about known harms and benefits has resulted in a bias towards screening and an inflated view of how much the reduction in cancer mortality can be attributed to cancer screening overall. Stefanek proposes that effort should be refocused on educating rather than persuading the public, engaging in SDM, working to create educational tools, and measuring success in terms of the number of patients informed rather than by the number of patients screened.

Zikmund-Fisher, Brian J. et al., “The DECISIONS Study: A Nationwide Survey of United States Adults Regarding 9 Common Medical Decisions” *Medical Decision Making* **September/October 2010 vol. 30 no. 5 suppl 20S-34S.**

Article that describes a survey of 3010 adults age 40 and older to assess the frequency of which they made decisions regarding 1) initiation of prescription medications for hypertension, hypercholesterolemia, or depression; 2) screening tests for colorectal, breast, or prostate cancer; and 3) surgeries for knee or hip replacement, cataracts, or lower back pain. The study found that 82.2 percent of participants reported making at least one medical decision in the preceding two years, with 83 percent making a decision about screening, 61 percent about medications, and 44 percent about surgery. The high frequency of medical decision making lends further weight to the importance of conducting shared decision making during routine care for these and other conditions.

OTHER RECOMMENDED CITATIONS

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 APPENDIX C: CITATIONS BY TOPIC

Below is a list, alphabetical by topic, of all the citations to appear in the paper. Links to these resources have been included where available (Note: some require subscriptions to review the full text).

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COMPANION DOCUMENT: STATE LEGISLATIVE AND REGULATORY APPROACHES TO
SHARED DECISION MAKING

The contents of this document include:

1. Washington State Senate Bill 5930 (2007): Shared Decision Making Segment
2. Washington State House Bill 1311
3. Washington State Senate Bill 1311 Report
4. Vermont Senate Bill 129 (2010)
5. Minnesota Healthcare Homes Published Rules
6. Minnesota Omnibus Bill: Patient-Centered Decision Making
7. Maine Board of Licensure in Medicine Informed Consent Guidelines

To view the companion document please follow this [link](#).

ENDNOTES

- 1 Dawn Stacey et al., "Decision aids for people facing health treatment or screening decisions," *The Cochrane Library*, Issue 10, (2011).
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