

**INTERIM REPORT**

**The Practice and Impact of Shared Decision-making**

Prepared by:  
The Shared Decision-making Study Group  
for the Dirigo Health Agency's Maine Quality Forum

Submitted to:  
Maine's Joint Standing Committee on Health and Human Services  
and the Joint Standing Committee on Insurance and Financial Services

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## **The Practice and Impact of Shared Decision-making**

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# EXECUTIVE SUMMARY

The 124<sup>th</sup> Maine State Legislature authorized the Maine Quality Forum to convene a Study Group to examine the benefits and use of shared decision-making in clinical practice. This Interim Report summarizes major activities of the Study Group and its preliminary conclusions.

## Major Activities

In preparation of this Interim Report, the Study Group undertook four major activities:

- **Review of Evidence-Based Literature** – The Study Group compiled and synthesized findings from research on shared decision-making. While much has been written on the practice, the Study Group focused its review on scientific clinical trials comparing the impact of shared decision-making to usual care of a control group.
- **Presentations by subject matter experts** – The Study Group heard from clinicians and consumers who practice shared decision-making, sponsors of pilots who are testing real world implementation, and researchers who study its impact.
- **Survey of Maine providers and payors** - To inform its understanding of the current and proposed use of shared decision-making in Maine, a survey was administered to major health systems, hospitals, provider groups and payors.

## Preliminary Conclusions

The Study Group adopted a definition that includes three factors that must be present for a process to be considered *shared decision-making*:

- The patient is faced with two or more treatment options with no clear best choice in terms of survival, outcome, or functionality;
- The patient’s own preferences and values drive decisions; and
- The patient and clinician share information with each other, take steps to participate in the decision, and agree on a course of action based on the patient’s preferences.

Using this definition, the Study Group developed preliminary conclusions for each of the topics requested in the Legislative Resolve.

- 1. The Study Group believes that shared decision-making applies to all preference sensitive conditions where patients are faced with two or more treatment options with no clear best choice.** Our research found many models of shared decision-making, some more comprehensive than others, with no nationally accepted protocol. In defining an accepted model, the Study Group believes that an ideal shared decision-making process includes:
  - a. A real time, face to face interaction between patients and their clinicians
  - b. Clarification of patient values and preferences
  - c. Balanced information and education about treatment options
  - d. Supportive guidance through the decision process.

- 2. No nationally recognized body exists to certify and/or oversee the use of decision aids and their effectiveness varies.** Findings on the effectiveness of decision aids are discussed in #5 and #6 below.
- 3. While advocating for reimbursement of shared decision-making, the Study Group identified multiple challenges to its implementation.** First, no standard exists for defining what constitutes an acceptable shared decision-making process which must be present in order to be reimbursed. Second, no national or local codes exist to document that the process took place. Third, there is incomplete evidence on the differential payment that should be received for implementing shared decision-making and who should be eligible for such payments.
- 4. Reimbursement would be a clear incentive to promote the use of shared decision-making.** Also, recognizing the practice of shared decision-making within pay for performance programs may raise the profile of shared decision-making and properly acknowledge its place in clinical practice. This could be done through use of the NCQA quality measure for shared decision-making. Further examination could also be given to modifying benefit design by creating consumer incentives to participate in the ideal process of shared decision-making as outlined in #1 above.
- 5. There is strong evidence that shared decision-making leads to higher quality of care as measured by patient satisfaction.** Shared decision-making focuses on situations where there is no best clinical choice. The risks and benefits of each choice can only be weighed within the context of a patient's own preferences and values. When effectively provided, shared decision-making provides the opportunity and structure for patients to receive and understand objective information on treatment options along with the risks and benefits of each, and to select the option that best matches their preferences. Studies show that patients do better when they are actively involved in these decisions. The alternative to shared decision-making is a return to a paternalistic system where choices are governed by the preferences and values of clinicians and not those of the patient who must live with the consequences.
- 6. The evidence is insufficiently strong to promote shared decision-making on the basis of saving costs.** Presently, findings from randomized clinical trials are the most credible bases for determining potential cost savings from the introduction of shared decision-making practices. As noted in this report, the impact of shared decision-making on cost is inconclusive. Four aspects of existing studies are especially troubling when trying to determine cost impact. First, studies necessarily provide a very controlled environment for testing the process and targeting patients who are most likely to benefit from the intervention. Secondly, studies do not fully account for all costs associated with shared decision, including the cost of the shared decision supports and tools, identifying, screening and contacting patients, training clinicians, and the additional time required by health care workers to incorporate shared decision-making into their patient encounter. Thirdly, cost savings identified through clinical studies do not examine a long enough time horizon to understand whether patients subsequently change their mind and later opted for more expensive procedures, whether substitution effects occur, and the appropriateness of service use on long term outcomes. Finally, clinical studies involving decision aids are subject to potential bias if conducted by the developer of those aids.

**7. The lack of reimbursement to adequately fund the time and resources needed to implement shared decision-making is the most frequently raised barrier to its implementation.** The Study Group found that other factors also serve as deterrents to its full adoption. There are no national standards for shared decision-making leading to substantial variation in its effectiveness. There is no nationally recognized body authorized to certify shared decision-making aids, further complicating a categorical endorsement of the concept. Outside of the controlled setting of clinical trials, there is no standardized documentation that would allow its use and impact to be routinely assessed.

## **Next Steps**

During the period leading up to this Interim Report, the Study Group grounded itself on the science and practice of shared decision-making. With this foundation, the Study Group now will turn its attention to specific strategies for promoting shared decision-making, focusing particularly on the role of state government. The Study Group will continue to monitor and learn from national and state-based demonstration projects to assure that our final recommendations to the Legislature reflect the latest experience and evidence.

## ■ BACKGROUND AND MISSION

The 124<sup>th</sup> Maine State Legislature adopted a Resolve requesting the Maine Quality Forum (MQF) to study the issue of shared decision-making.<sup>1</sup> Specifically, the Resolve required the MQF to establish an advisory group to consider:

1. The appropriate preference-sensitive health care services for use in a shared decision-making program and an accepted protocol for shared decision-making;
2. The availability of approved patient decision aids relating to each health care service and the effectiveness of patient decision aids;
3. The payment method to be used by health insurance carriers and public programs to reimburse for services provided by a shared decision-making program;
4. The appropriate incentives to encourage use of a shared decision-making program by providers and patients;
5. Evidence-based studies that evaluate shared decision-making; and
6. Any barriers to implementation of a shared decision-making program

The Resolve requested that the Advisory Group submit an interim report to the Joint Committee on Health and Human Services and the Joint Standing Committee on Insurance and Financial Services by early 2010 with a final report due in 2011. The following report summarizes the work of the Maine Quality Forum in response to the Resolve and provides interim conclusions and proposals for moving forward.

## ■ SHARED DECISION-MAKING STUDY GROUP

In September 2009, the MQF established a Shared Decision-making Study Group in accordance with the composition required in the Resolve. Nominations were solicited from MaineCare, the Maine Health Data Organization, the Maine Hospital Association, the Maine Medical Association, and the Maine State employee health insurance program. In addition, the MQF solicited participation from legislators, researchers with an interest in shared decision-making, and practitioners and consumers involved in preference sensitive care. APPENDIX A lists the members of the Study Group and their affiliations.

The first meeting of the Study Group was held on October 13, 2009. Three additional in-person meetings were convened during the period covered by this interim report. Study Group meetings were open to the public and findings reported back to the Maine Quality Forum Advisory Council. The final report represents a consensus of the Study Group except where otherwise noted in the Report.

## ■ MAJOR ACTIVITIES AND FINDINGS

Based on the parameters established in the Legislative Resolve, the Study Group organized its activities to address four major questions:

- What is shared decision-making?
- What is the current state of practice?
- What are the challenges to implementation?
- How does shared decision-making impact health care quality and costs?

The Study Group relied on the literature and subject matter experts in their deliberations. This included discussions with those involved in a pilot on shared decision-making in Washington State, an initiative around which Maine's Resolve was partially based. The Study Group is particularly grateful to the following experts who shared generously of their knowledge about the science of shared decision-making and its implications for practice.

*Nananda Col MD*, Senior Scientist and Director, Center for Outcomes Research and Evaluation at the Maine Medical Center

*Moritz Hansen MD*, Medical Director of the Maine Medical Center Cancer Institute Genitourinary Cancer Program

*Terry Kungel*, consumer

*Jana Purrell*, Practice Administrator, Mid-Coast Medical Group

*Leah Hole-Curry JD*, Director, Health Care Technology Assessment, Washington State Health Care Authority.

*Neil Korsen MD*, Medical Director, Clinical Integration Division, MaineHealth

*Richard Wexler MD*, Director, Patient Support Strategies, Foundation for Informed Decision-Making

To inform its understanding of the current and proposed use of shared decision-making in Maine, a survey was administered to major health systems, hospitals, provider groups and payors [see APPENDIX B for the survey]. Major findings of the Study Group's efforts are described below, followed by a fuller discussion of the Group's preliminary conclusions and next steps.

### **What is shared decision-making?**

The Study Group spent considerable time establishing a working definition for shared decision-making based on the literature and current practice, which could guide its work. While definitions vary, researchers generally agree that three essential factors must be present for a process to be considered *shared decision-making*:

- The patient is faced with two or more treatment options with no clear best choice in terms of survival, outcome, or functionality.
- The patient's own preferences and values drive decisions.
- The patient and clinician share information with each other, take steps to participate in the decision, and agree on a course of action based on the patient's preferences.<sup>2</sup>

The term *shared decision-making* is often mistakenly used interchangeably with *informed decision-making* – a broader term referring to patients becoming more knowledgeable about their health care and treatment decisions in general.<sup>3</sup> The distinction is an important one worth reinforcing. Shared decision-making occurs in cases where a patient’s *values and preferences* are the determining factors in deciding between two or more medically reasonable alternatives. Informed decision-making, on the other hand, is an effort to advance a patient’s understanding of the *science-base* for choosing one treatment option over the other.

Shared decision-making is a process of interaction to better match a patient’s preferences with the treatment he or she receives. The process connects the clinician’s understanding of the risks, benefits, and uncertainties of each treatment option with the patient’s goals, preferences and life values. Since by definition there is no *best* treatment choice in cases where shared decision-making is used, the process relies on the experience and expertise of both parties to find a mutually satisfactory decision.

Decision aids, including videos, interactive web programs, or printed material, may be used as an adjunct in shared decision-making. Aids are intended to provide objective and easy to understand information about treatment options, the likely physical and emotional consequences of each option, and their potential harm and benefit. Aids may also include tools to assess personal values and preferences. Decision aids help ground but are not a replacement for direct conversation between a clinician and patient to determine the preferred course of action.

## **What is the current state of practice and initiatives?**

### **Nationally**

Spurred by the consumer advocacy movement of the 1970s, the former paternalistic attitude that only clinicians know what is best for their patients has given way to a recognition that patients have a critical role to play in their medical care. Nowhere is that role greater than in conditions for which there is no single best medical approach to treatment. Such areas, often referred to as *preference sensitive care*, include certain decisions about managing early stage cancers, symptoms of menopause, and back pain, where patient values and goals should govern treatment decisions. The Dartmouth Institute for Health Policy and Clinical Practice defines preference-sensitive care as those “treatments that involve significant tradeoffs affecting the patient’s quality and/or length of life. Decisions about these interventions – whether to have them or not, which ones to have – ought to reflect patients’ personal values and preferences, and ought to be made only after patients have enough information to make an informed choice.”<sup>4</sup>

Nationally, there are limited data about the extent to which shared decision-making is incorporated into current medical practice since the process is not reimbursed and not typically documented by providers. One researcher, through a review of office visit audio tapes, found surgeons more likely to engage in informed decision-making than primary care physicians. But even among surgeons, only about 10 percent fully engaged patients in decision-making.<sup>3</sup> More information is needed about how shared decision-making is being practiced since no standard exists against which it is measured. Variation in practice (and potential impact on quality and costs) can be significant - ranging from the simple viewing

of a video by a patient to a systematic process of personal exchanges between a clinician and patient to clarify treatment options that best align with the patient's preferences and values.

Despite having limited information on shared decision-making processes, we know that decision aids are growing in number and popularity. Repositories of aids can be found online for access by providers and patients.<sup>5-7</sup> Some are proprietary; others exist in the public domain. No recognized process exists for certifying decision aids although resources are available comparing the scope and features of existing decision aids and, where available, findings from clinical trials. The Cochrane Decision Aid Registry includes all decision aids that have been subject to randomized clinical trials in which the outcomes of their use are compared to no intervention, usual care and alternative interventions.<sup>5</sup> The International Patient Decision Aid Standards (IPDAS) Collaboration is a group of researchers, practitioners and stakeholders from around the world whose goal is to establish an internationally approved set of criteria to determine the quality of patient decision aids. Decision aids are rated on a number of criteria related to content, development process, and effectiveness. The Ottawa Hospital Research Institute is an online resource to help consumers and clinicians learn about decision aids and their quality. Tools and training are also available on the Ottawa site for clinicians wanting to incorporate aids in their practices.<sup>6</sup> The Foundation for Informed Medical Decision-making provides an online library of decision aids licensed and distributed by the firm Health Dialog, Inc.<sup>7</sup>

The National Committee for Quality Assurance (NCQA), a leading developer of standardized measures to assess performance of the health care system, has developed a shared decision-making measure to assess a patient's satisfaction with the decision-making process in cases where there was more than one reasonable treatment option. The composite measure is based on consumer responses to the Consumer Assessment of Health Care Providers and Systems or CAHPS survey.<sup>8</sup>

### **In other states**

The Study Group investigated initiatives in other states related to shared decision-making. Key among them is Washington State which, in 2007, was the first state to pass legislation formally recognizing shared decision-making in the state's laws on informed consent and encouraging collaborative efforts to develop, certify, use, and evaluate decision aids.<sup>9</sup> The legislation authorized the Washington State Health Care Authority to conduct a demonstration pilot to study the impact of using decision aids for identified preference-sensitive health care services on health care expenditures and patient satisfaction and understanding.<sup>10</sup>

Leah Hole-Curry, Director of Health Information Technology at the Washington Health Care Authority, updated the Study Group on the four site pilot at Group Health and the University of Washington. The Study Group learned that the decision aids being used in the pilot are limited to those meeting quality standards and which are being provided free of charge by their developer and study funder, Foundation for Informed Medical Decision-Making (FIMDM) and commercial distributor, Health Dialog. At the Group Health demonstration sites, patients whose condition falls within preference sensitive care areas addressed in the pilot\* are "prescribed" access to an online decision aid (typically a video) for viewing

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\* Preference sensitive conditions addressed in the pilot include: treatment choices for hip osteoarthritis, knee osteoarthritis, coronary artery disease, benign prostatic hyperplasia, prostate cancer, uterine fibroids, abnormal

prior to an appointment with a clinician. The trigger for determining when a decision-aid is “prescribed” varies by service and condition, and is based on the discretion of the primary care provider or specialist. An electronic mail system automatically records when a patient completes the video – documentation that the patient has been fully informed of the risks and benefits of treatment options. An important component of the Group Health demonstration is the shared decision-making which happens with the clinician after exposure to the decision aid. Although similar to work flow and trigger, the four-site demonstration at the University of Washington does not have linkage to the electronic medical record.

Some Study Group members expressed reservations that only decision aids developed by FIMDM/Health Dialog were chosen and assessed for the pilot. Some members questioned whether the pilot had adequate controls for selectively targeting the subset of patients for whom decision aids are most appropriate and how outcome measures will evaluate impact on costs, health services use, and efficiency. Despite these concerns, the Study Group saw the Washington State pilot as an important contribution for helping Maine better understand how shared decision-making can be effectively implemented in clinical practice and its impact on quality.

### **In Maine**

To understand the use of shared decision-making in Maine, the Study Group surveyed and heard directly from local clinicians about their efforts and development plans. The survey, administered by the Muskie School to major health care providers and payors, found no organizations with institutional policies or guidelines governing the practice or payment of shared decision-making.<sup>11</sup> However, “pockets” of practice were found, most notably in the areas of breast and prostate cancer treatment and bariatric medicine. More generally, survey respondents discussed the value and use of tools and techniques to solicit patient engagement in their medical treatment decisions, a process more aligned with informed decision-making.

The Study Group also learned firsthand from the Maine Medical Center Genitourinary Cancer Program about their commitment to shared decision-making in the treatment of prostate cancer patients.<sup>12</sup> The program uses an oncology nurse to help patients navigate through the many decisions faced as part of the treatment process and to support them in living with the decision after it is made. The clinical “navigator” is an independent patient advocate working collaboratively with the patient and clinician to identify and implement treatment options meeting a patient’s preferences and values. The value of the navigator approach to shared decision-making was reinforced by a consumer and Study Group member. Time and resources required to implement the program are not reimbursable and are funded by the Maine Medical Center.

As part of its national demonstration, the Foundation for Informed Medical Decision-making recently awarded \$185,540 to MaineHealth to help patients use decision aids, licensed and distributed by Health Dialog Inc., to make complex medical decisions in coordination with their physicians. Participants in the study will be identified through an electronic medical record system. Health educators located at

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uterine bleeding, early stage breast cancer, breast reconstruction, ductal carcinoma in situ, low back pain, spinal stenosis, and herniated disc.

MaineHealth’s Learning Resource Center will be available to support patients' use of these materials and answer questions.<sup>13</sup> A major goal of the project is to learn more about how to implement shared decision-making as part of routine primary care practice.<sup>14</sup>

Another Maine-based study will directly compare different types of decision aids (decision cards versus video and/or print) as well as different approaches to integrating shared decision-making in practice (use of decision aid alone, with a navigator/coach, with a physician). Focused on shared decision-making for “low risk” prostate cancer and low back pain, this collaborative study<sup>†</sup> will assess outcomes related to treatment choice, health service use, cost and cost-effectiveness.<sup>15</sup>

The Maine Patient-Centered Medical Home pilot recently announced that technical assistance will be made available to support the 26 participating primary care practices in implementing patient shared decision-making for preference sensitive care (Email correspondence with Lisa Letourneau, MD, February 24, 2010). These resources are being made available to support practices in their effort to transform to a more patient-centered model of care and to meet the core expectations of the pilot.

The Maine Health Management Coalition completed Phase 1 of a two-part study to develop a research and education program for shared decision-making for minimally invasive procedures.<sup>16</sup> Funded by Ethicon Endo, a manufacturer of minimally invasive surgical equipment, the study conducted surveys and interviews with local physicians and a consumer focus group to assess the content and administration avenues for decision aids developed by Ethicon Endo. The study noted that the effectiveness of shared decision-making very much relies on changing the behaviors of physicians, staff and patients as consumers become more engaged parties in the decision-making process. A materials distribution strategy will be developed in Phase 2.

## **What are the challenges to implementation?**

Muskie School survey respondents identified challenges to implementing shared decision-making similar to those found in the research literature. Most commonly cited challenges include:

**Time** - A lack of time for prolonged clinical interactions with patients is a primary concern when trying to integrate shared decision-making into clinical practice.<sup>17,18</sup> Although generally considered to be a time consuming proposition, studies differ on whether shared decision-making increases the interaction time between patient and physician.<sup>17,18</sup>

**Provider training** - Shared decision-making is a new concept for providers and has not been modeled in practices or medical schools. Physicians need training in the use of decision aids and guidance in how to initiate the process.<sup>18,19</sup> They also need to differentiate shared decision-making from informed decision-making. Results from the Muskie School survey revealed that many physicians mistakenly believe they are already practicing shared decision-making with their patients when providing

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<sup>†</sup> Study collaborators include Maine Medical Center’s Genitourinary Cancer Program, Maine Medical Partners Neurosurgery and Spine programs, Maine Medical Center’s Center for Performance Improvement and Maine Medical Center’s Center for Outcomes Research and Evaluation.

information on treatment options. As one respondent stated, “I am quite sure our breast surgeons use shared decision-making. They present the patients with the pros and cons of breast conservation versus mastectomy... They ... obtain informed consent at that time if the patient is ready to make a decision. Otherwise the patient is sent with reading material and will call once they have reached a decision.”

**Reimbursement** – With more time and resources required, providers understandably look for increased compensation when implementing shared decision-making in their practices. Nationally, there is no system of reimbursement in place<sup>17,19</sup> With the assistance of Jana Purrell, a former consultant specializing in medical coding, the Study Group examined possible codes for reimbursing time devoted to shared decision-making. The Group was advised that there are no standard or local codes specific to shared decision-making but that codes for evaluation and management may be applicable. Time-based evaluation and management codes can be used if more than half of the visit is spent in counseling and/or coordination of care. To code based on time, there must be documentation of the total time spent with the patient, the amount of time spent in counseling/coordination of care, and a detailed description of what was discussed. Alternatively, a clinician could use a general code for an evaluation and management visit if the visit also includes history taking, physical exam and medical decision-making. (Email correspondence with Jana Purrell, March 29, 2010.)

There is a perception among some that shared decision-making simply represents good practice and should not receive differential payment. One payor responding to the Muskie School survey noted: “Good practitioners should be discussing all treatment options and the pros/cons...with their patients already, without requiring legislative action that may have unintended consequences (i.e. more administrative procedures, reporting, paperwork, etc. for both practitioners and health plans that will increase administrative costs).”

**Targeting the right patients** - Shared decision-making is only appropriate in certain circumstances even when patients have similar diagnoses. First, it applies only where there are multiple options and no best choice, such as during earlier stages of a disease process.<sup>‡</sup> Secondly, not all patients are receptive or able to fully participate in shared decision-making. Some patients lack the ability to comprehend complicated medical information. Others prefer that the clinician be in charge of the decision. Given that shared decision-making comes at an already stressful time for a newly diagnosed patient, some patients are unable to take on the added responsibility of directing their treatment choice. Clinicians must be sensitive to the emotional, physical and intellectual capacity of their patients and match the level of decision-making involvement to the individual patient.<sup>20</sup> While recognizing that patients have a right to shared decision-making, the process of involvement often relies on the comfort level of physicians in tailoring a process to the needs of a patient. This variable process may deter clinicians from engaging in shared decision-making.<sup>18</sup> Conversely less selective methods of choosing patients, such as automated mailings of decision aids to patients based on diagnoses recorded in their records, carries with it the risk of inappropriate patient selection. The fact that even the provision of health care information is in itself a medical intervention reinforces the need for careful patient selection, and the importance of clinical context.

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<sup>‡</sup> Evidence in favor of a certain treatment is often emphatic in later stages of a disease.

## How does shared decision-making impact costs and quality?

In its Resolve, the Maine Legislature expressed specific interest in understanding the potential for shared decision-making to improve the quality of care and reduce unnecessary use of medical services. The literature generally supports the premise that shared decision-making improves quality but is mixed on the question of its impact on costs.

### Quality

Most stakeholders agree that shared decision-making is “the right thing to do” because it improves care by empowering the patient to be involved in decisions. One study found that 78.5 percent of patients wanted to be involved in the decision-making process.<sup>21</sup> Many researchers have concluded “Patient centered decision-making is an important component to quality of care and is closely linked to patient satisfaction”.<sup>22</sup> While most found that satisfaction will increase because choices tend to be a better match to patients' values, other studies came to a different conclusion.<sup>23</sup> Researchers with the Cochrane Collaboration, after a review of randomized controlled trials, reported that decision aids as an adjunct to shared decision-making have no effect on satisfaction. However, the review showed that decision aids “improve people’s knowledge of the options, create accurate risk perceptions of their benefits and harms, reduce difficulty with decision-making, and increase participation in the process.”<sup>23</sup> Despite conflicting findings on satisfaction, studies find it crucial to gauge a patient's interest and ability to be involved in decision-making. Satisfaction will decrease when involvement in decision-making becomes burdensome to the patient; it may even increase anxiety.<sup>20</sup>

A number of studies reported beneficial health outcomes among patients after shared decision-making. Women with breast cancer, for example, tended to have improvement in overall quality of life, including fewer side effects and better physical functioning, after taking an active role in their treatment decisions.<sup>24-26</sup> In another trial, involvement in shared decision-making improved health behaviors such as diet, exercise, smoking cessation, and alcohol consumption among women counseled in menopausal treatment options.<sup>27</sup> These studies conclude that patients do better when they are involved in their own care. The Cochrane Collaboration, however, found conflicting evidence that patient health or adherence to chosen treatments improve after a shared decision-making process. They cited studies comparing decision aids to routine care and found no difference in how often patients followed the chosen treatment.<sup>28</sup> However, there is clear evidence that shared decision-making increases knowledge, improves understanding of risks and benefits of treatment options, increases confidence in decision-making, and results in a choice more in line with patient values.<sup>2</sup>

The Shared Decision-making Workgroup of the U.S. Preventative Services Task Force recommends shared decision-making on several grounds: it promotes the ethical treatment of patients by protecting their autonomy; it educates patients about health information; it reduces decisional conflict; and it fosters trust in the health care provider.<sup>17</sup> For over a decade, the American Cancer Society has endorsed shared decision-making, specifically for prostate screenings and ovarian cancer.<sup>29</sup> The Society cites studies showing most patients also prefer to engage in shared decision-making rather than leave treatment decisions to their doctors.<sup>30</sup> With the complexity of many cancer screening recommendations, such as prostate specific antigen (PSA) screening and mammograms, the American Cancer Society endorses shared decision-making as a way for clinicians to discuss risks and benefits of screenings with patients and arrive at a mutually agreeable decision.

## Cost

Research by the Dartmouth Institute for Health Policy and Clinical Practice (formerly the Center for Evaluative Clinical Sciences) demonstrated “wide variations in what Medicare spends for services to treat chronically ill patients and that higher spending does not achieve better outcomes”.<sup>31</sup> Findings included evidence that there are higher rates of elective invasive procedures in some regions of the country, with no improvement in quality of care or patient satisfaction with care.<sup>4</sup> This is not surprising since incentives in medical practice are tied to the procedure performed and not quality.<sup>32</sup> Shared decision-making offers a possibility to reduce costs associated with *preference-sensitive* procedures by allowing patients a role in choosing a treatment based on their values. Studies suggest that patients, when given a choice, tend to favor less invasive procedures.<sup>4,23</sup>

The Cochrane Collaboration review concluded that rates of elective surgery, menopausal hormone usage, and prostate specific antigen (PSA) screenings were lowered as a result of shared decision-making with use of a decision aid.<sup>23</sup> For example, because PSA screenings will sometimes detect “low risk” prostate cancers for which there is no best decision on treatment, “watchful waiting” is often favored by patients after undergoing a shared decision-making process.<sup>33</sup> However, the impact was modest and inconsistent, with some trials finding decision aids increase breast and colorectal cancer screening rates.<sup>34</sup> If cancer is detected after a screening, an invasive procedure may not result in a better long-term outcome for a patient, but it will cost a great deal more.<sup>32</sup> While there is no way to predict what treatment a patient will choose after participating in shared decision-making, since information will be presented impartially, evidence that aggressive procedures may decline as a result of shared decision-making is encouraging. The Washington State pilot is assessing the impact of decision aids developed by a specific vendor, so more conclusive evidence may be forthcoming.<sup>10</sup>

The Lewin Group applied existing studies to estimate potential savings among Medicare patients with any of 11 conditions who used decision aids. However, their estimated savings of \$4,083M over a ten-year period assumed that there would be a co-payment penalty if patients chose a higher cost procedure where a less costly procedure was as effective. The analysis also assumed a “denial of payments to physicians and hospitals for higher-cost services performed when a lower-cost alternative of at least the same effectiveness is available”.<sup>35</sup>

Studies on cost impact generally do not account for the increased expense of purchasing decision support tools such as interactive video disks, screening for appropriate patients, training clinicians, and implementing neither procedural changes nor the clinical time required to participate in the process. While there are ways to minimize costs by having nurses coach patients, for example, or using less costly or free tools, additional costs are likely.<sup>2</sup> Increased interaction time with physicians may also increase costs, although trials cited in the Cochrane Database of Systematic Reviews found conflicting evidence that use of a decision aid increases consultation times.<sup>36</sup> One study found consultations increased by six minutes when a decision aid and shared decision-making were used.<sup>37</sup> Another found interaction time was eight minutes shorter when similar consultation techniques were used.<sup>38</sup> Testing these outcomes in real world settings rather than controlled trials would help determine average consultation time for shared decision-making and how it would impact cost.

Cost savings identified through clinical studies do not examine a long enough time horizon to understand whether patients subsequently change their mind and later opt for more expensive procedures or whether substitution effects occur (e.g., less invasive procedures may be accompanied by more use of other tests or clinical services) as was demonstrated in one study which tracked these outcomes.<sup>39</sup>

Although research on the subject has failed to show conclusive cost savings associated with shared decision-making, there are several other areas of promise. Some studies show patients actively involved in health-related decisions tend to have better health outcomes<sup>25,26</sup> This could reduce the need for follow up care or more costly interventions if these findings can be demonstrated in real world practice. Shared decision-making, as a component of informed consent may also reduce malpractice and liability claims, since the creation of a collaborative partnership in decision-making may make patients feel more empowered and less likely to hold a health provider liable should a complication occur.<sup>40</sup> More research is needed to prove this hypothesis.

## ■ PRELIMINARY CONCLUSIONS

A primary goal of the *Interim Report* was to synthesize the major work and findings of the Study Group on the science and practice of shared decision-making. The Legislative Resolve also asked the Study Group to provide preliminary guidance on the value of shared decision-making in enhancing quality and reducing costs in Maine. Based on its work to date, the Study Group has reached the following preliminary conclusions.

**Shared decision-making offers a beneficial approach that, when effectively implemented, links a patient’s preferences and values with a clinician’s evidence-based knowledge of the risks, harm and benefits of each treatment option to arrive at a good decision.**

The evidence is clear that there is a category of conditions, often referred to as *preference-sensitive* care, around which there is no single best medical approach to treatment. In these cases, only the patient can weigh the risks, harms and benefits of each treatment option against his or her own values and preferences.

Most medical decisions rely on the expertise and experience of a clinician to determine the available options and best course of action. Although patients may be highly informed on matters of their medical options, a patient’s perspective rarely tips the scales when evidence points to one clearly superior choice. In the case of preference sensitive care, however, it is the patient’s perspective that should be the deciding factor in choosing among options. When effectively developed and implemented, shared decision-making provides the structure and tools to select an option that best meets a patient’s preferences and values.

**With respect to each of the issues raised in the Legislative Resolve, the Study Group found the following.**

- 1. Identify the appropriate preference-sensitive health care services for use in a shared decision- making program and an accepted protocol for shared decision-making.**

**The Study Group believes that shared decision-making applies to all preference sensitive conditions where patients are faced with two or more treatment options with no clear best choice.** Our research found many models of shared decision-making, some more comprehensive than others, with no nationally accepted protocol. In defining an accepted model, the Study Group believes that an ideal shared decision-making process includes:

- e. A real time, face to face interaction between patients and their clinicians
- f. Clarification of patient values and preferences
- g. Balanced information and education about treatment options
- h. Supportive guidance through the decision process.

The Study Group found that shared decision-making is often mistakenly equated with the use of decision aids. Further advancement of the concept should be careful to emphasize the importance of shared decision-making as a process where decision aids are considered an adjunct, not a replacement, for in-person discussion and decision-making.

- 2. Determine the availability of approved patient decision aids relating to each health care service and the effectiveness of patient decision aids.**

**No nationally recognized body exists to certify and/or oversee the use of decision aids.** Clinical studies on shared decision-making largely have focused on the use of decision aids. Findings from these studies are discussed in #5 below.

- 3. Propose a payment method to be used by health insurance carriers and public programs to reimburse for services provided by a shared decision-making program.**

**While advocating for reimbursement of shared decision-making, the Study Group identified multiple challenges to its implementation.** First, no standard exists for defining what constitutes an acceptable shared decision-making process which must be present in order to be reimbursed. Second, no national or local codes exist to document that the process took place. Third, there is incomplete evidence on the differential payment that should be received for implementing shared decision-making and who should be eligible for such payments.

- 4. Identify appropriate incentives to encourage use of a shared decision-making program by providers and patients.**

**Reimbursement would be a clear incentive to promote the use of shared decision-making.** Also, recognizing the practice of shared decision-making within pay for performance programs may raise the profile of shared decision-making and properly acknowledge its place in clinical practice. This could be done through use of the NCQA quality measure for shared

decision-making. Further examination could also be given to modifying benefit design by creating consumer incentives to participate in the ideal process of shared decision-making as outlined in #1 above.

## 5. Research evidence-based studies that evaluate shared decision-making.

### *Impact on Quality*

**There is strong evidence that shared decision-making leads to higher quality of care as measured by patient satisfaction.** Shared decision-making focuses on situations where there is no best clinical choice. The risks and benefits of each choice can only be weighed within the context of a patient's own preferences and values. When effectively provided, shared decision-making provides the opportunity and structure for patients to receive and understand objective information on treatment options along with the risks and benefits of each, and to select the option that best matches their preferences. Studies show that patients do better when they are actively involved in these decisions. The default to shared decision-making is a return to a paternalistic system where choices are governed by the preferences and values of clinicians and not those of the patient who must live with the consequences.

### *Impact on Cost*

**The evidence is insufficiently strong to promote shared decision-making on the basis of saving costs.** Presently, findings from randomized clinical trials are the most credible bases for determining potential cost savings from the introduction of shared decision-making practices. As noted in this report, the impact of shared decision-making on cost is inconclusive. None of the studies to date are robust – some suggest an increase in cost, others a decrease. Four aspects of existing studies are especially troubling when trying to determine cost impact. First, studies necessarily provide a very controlled environment for testing the process and targeting patients who are most likely to benefit from the intervention. In the real world of clinical practice, there is likely to be far less adherence to patient selection protocols. There is the potential for poorer cost and quality outcomes as patients with complicated medical factors, histories or special circumstances become participants in the process. Secondly, studies do not fully account for all costs associated with shared decision, including the cost of the shared decision supports and tools, identifying, screening and contacting patients, training clinicians, and the additional time required by health care workers to incorporate shared decision-making into their patient encounter.

Thirdly, cost savings identified through clinical studies do not examine a long enough time horizon to understand whether patients subsequently change their minds and later opted for more expensive procedures, whether substitution effects occur, and the appropriateness of service use on long term outcomes. Finally, clinical studies involving decision aids are subject to potential bias if conducted by the developer of those aids. Similar to clinical studies sponsored by the pharmaceutical industry that may be testing a commercial drug or device, the same standard for potential conflict of interest, real or perceived, applies to products promoting shared decision-making.<sup>16</sup>

## 6. Identify barriers to implementation of a shared decision-making program

**The lack of reimbursement to adequately fund the time and resources needed to implement shared decision-making is the most frequently raised barrier to its implementation.**

The Study Group found that other factors also serve as deterrents to its full adoption. There are no national standards for shared decision-making leading to substantial variation in its effectiveness. There is no nationally recognized body authorized to certify shared decision-making aids, further complicating a categorical endorsement of the concept. Outside of the controlled setting of clinical trials, there is no standardized documentation that would allow its use and impact to be routinely assessed.

Respondents to the Muskie School survey confirmed that the practice of shared decision-making is often confused with general patient engagement in medical care. Findings from the first phase of the Maine Health Management Coalition study found that misperceptions also exist among consumers about when, whether and how to become full partners in preference sensitive care decisions. These findings suggest that further education and training will be needed for shared decision to fully reach its potential.

## ■ NEXT STEPS

During the period leading up to this Interim Report, the Study Group grounded itself on the science and practice of shared decision-making. With this foundation, the Study Group now will turn its attention to specific strategies for promoting shared decision-making, focusing particularly on the role of state government. The Study Group will continue to monitor and learn from national and state-based demonstration projects to assure that our final recommendations to the Legislature reflect the latest experience and evidence.

## End Notes

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## APPENDIX A

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# APPENDIX B

## Shared Decision-making Survey

### REQUEST FOR INFORMATION

#### Use and Payment of Shared Decision-making in Maine

##### Background

During its last session, the Maine legislature authorized the Maine Quality Forum to convene an advisory group to study the issue of shared decision-making and to make recommendations on a strategy for promoting its use in Maine. One aspect of their work is to better understand the extent to which shared decision-making is currently used in Maine and reimbursement methods that are available.

##### Definition

The Shared Decision-making Study Group generally agreed that shared decision-making occurs when patients are faced with two or more treatment options with no clear best choice in terms of survival, outcome, or functionality. The following working definition has been adopted.

*A decision-making process jointly shared by patients and their health care provider.*

The group recognizes that other forms of enhanced decision-making exist including informed decision-making and that current terminology is imprecise. We are interested in how improved patient decisions are being supported in Maine.

##### Purpose of Survey

The following survey is being sent to major payers in Maine and large health systems in Maine and nationally. Information obtained from the survey will be used to assess current opportunities and barriers to implementing shared decision-making and to inform recommendations to the Maine State Legislature.

1. Person completing the survey [name, title, email address]
  
2. Name of organization
  - a. Name
  - b. Type
    - i. Health care provider
    - ii. Payor
    - iii. Other (please specify)

3. Does your organization have current policies or guidelines governing the practice or payment of shared decision-making?
  - a. Yes
  - b. No (Skip to Q7)
4. Are current policies or guidelines limited to specific clinical services, settings or practitioners?
  - a. Yes (please describe)
  - b. No
5. Please describe the purpose and scope of current policies or guidelines. [open text]
6. If applicable, please provide the definition of shared decision-making included in current policy or guidelines. [open text]
7. Is your organization actively considering the development of policy or guidelines governing the practice or payment of shared decision-making?
  - a. Yes
  - b. No (Skip to Q11)
8. Please describe the nature of that activity, participants, timelines, and expected products. [open text]
9. If applicable, please provide the working definition of shared decision-making that is being used in these activities. [open text]
10. Please describe any current or proposed methods that have been developed to document the occurrence of shared decision-making, such as new codes or other data entry. [open text]
11. Please describe the major barriers you see to the use and payment of shared decision-making among practitioners and patients? [open text]
12. The Shared Decision-making Study Group welcomes your input. Please describe any legislative or other statewide action that you believe would enhance the use of shared decision-making in Maine. [open text]