

Shared Decision Making

Health Services and Medical Management Division

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Executive Summary

While some positive results from the use of patient decision aids (PtDAs) and shared decision-making (SDM) are encouraging, the vast majority of clinical trials involving PtDAs and SDM have not shown significant results. Lack of definition and standardization regarding currently available tools, coupled with concerns regarding keeping PtDAs current with the scientific literature, pose problems to the immediate integration of these tools beyond a research setting. While the intent of PtDAs and SDM is laudable, there are many unanswered questions regarding how best to use these tools. Concern regarding premature requirements for SDM highlights a risk of provider and patient backlash, despite potential benefits to both.

There is now an active, community-wide multi-stakeholder group (the Minnesota Shared Decision Making Collaborative), working to develop, implement, and evaluate SDM in medical practices throughout Minnesota. See Attachment 1 for the report from this group. It is suggested that policies related to SDM focus on facilitating and evaluating the results of this collaborative work rather than mandating or requiring SDM.

The purpose of this document is:

- To evaluate the efficacy of shared decision-making and patient decision aids on health care quality, patient satisfaction, and health care costs;
- To discuss the current level of effectiveness of SDM and PtDAs in clinical practice outside of the research environment; and
- To present recommendations for policy options to promote the use of SDM in clinical practice.

Introduction

Policy Context

In the 2008-2009 Minnesota legislative session, the following law was passed (256B.0625, subdivision 3c): **Patient Centered Decision Making:** The Health Services Policy Committee shall study approaches to making provider reimbursement under the Medical Assistance, MinnesotaCare, and General Assistance Medical Care (GAMC) programs contingent on patient participation in a patient-centered decision-making process, and shall evaluate the impact of these approaches on health care quality, patient satisfaction, and health care costs. The committee shall present findings and recommendations to the commissioner and the legislative committees with jurisdiction over health care by January 15, 2010.

Background

Many decisions in health care are “preference-sensitive,” defined as having the best choice dependent on the patient’s values or preferences for the benefits, harms, and scientific uncertainties of each option (Wennberg et al, 2002). These decisions do not have clear answers because the benefit/harm ratios are either scientifically uncertain or are sensitive to patients’ values. There can be wide variations in practice patterns in the use of preference-sensitive options. For example, the likelihood of having a lumpectomy for early stage breast cancer varied regionally between 12% and 48% among Medicare women (Center for the Evaluative Clinical Sciences, 2007).

When the “best” therapeutic option is unclear, a patient-centered or shared decision-making (SDM) style of counseling has been advocated (O’Connor et al, 2004). This involves practitioners communicating personalized information on options, outcomes, probabilities, and scientific uncertainties, and patients communicating the personal value or importance they place on benefits versus harms so that agreement on the best strategy can be reached. Shared decision-making is often positioned as a “middle ground” between paternalism (i.e., physicians make the decisions) and informed choice (i.e., patients make the decisions) (Makoul et al, 2005). To facilitate the process, evidence-based patient decision aids (PtDAs) have been developed as adjuncts to counseling.

PtDA development has utilized diverse formats including print, video and audio media, have been administered in self- or practitioner-administered situations, and have been used in one-on-one or group situations. There are three key elements common to the design of PtDAs: 1) Information provision, 2) values clarification, and 3) guidance in deliberation and communication (O’Connor, 2004).

With the rapid proliferation of these tools, the International Patient Decision Aids Collaboration (IPDAS) has reached agreement on criteria for judging the quality of PtDAs (O'Connor, 2007). IPDAS, a network of more than 100 researchers, practitioners, patients, and policy makers from 14 countries, has developed a checklist of criteria for PtDAs that addresses three domains of quality: clinical content, the development process, and effectiveness (Elwyn et al, 2006).

Body of Report

Three systematic reviews (SR) of the effects of shared decision making (SDM) and/or patient decision aids (PtDAs) were identified for analysis. These are: a 2009 Cochrane Collaboration SR evaluating 55 studies on 23 screening or treatment decisions, a SR evaluating 11 studies on SDM for prostate-specific antigen testing, and a 2007 meta-analysis by the American Society for Clinical Oncology evaluating 11 studies on SDM for early-stage breast cancer. In addition, a number of studies related to utilization of decision aids in clinical practice were included in this analysis. The findings are described, below.

Systematic Reviews

Cochrane Collaboration 2009

A recently updated systematic review from the Cochrane Collaboration evaluated 55 randomized clinical trials (RCTs) from seven countries using 51 separate decision aids that evaluated 23 different screening or treatment decisions. (O'Connor, 2009). Results of RCTs were pooled using mean differences (MD) and relative risk (RR) using a random effects model.

According to this review, decision aids were correlated with better results related to patient knowledge and indecision, but no difference was found related to anxiety or decisional regret. Regarding health care quality and costs, decision aids were associated with statistically significant differences for prostate-specific antigen (PSA) testing for prostate cancer, use of Hepatitis B vaccines, and menopausal hormones. Findings were mixed for patient perceptions regarding relief from complications of back pain, patient attitudes toward their general health, patient perceptions of their ability to perform their physical role, and satisfaction with health status. No statistical difference was found related to patient adherence with several therapies (including warfarin vs. aspirin, blood pressure medication, and hormone replacement therapy), patient preference for a number of therapeutic options (including pre-operative autologous blood donation, medication for hypertension, and vaginal birth following previous C-section), or health outcomes related to 12 different measures (including angina – 10 studies, bodily pain – 3 studies, genetic testing for breast cancer – 4 studies, colon cancer screening – 3 studies, and urinary symptoms – 4 studies).

The SR also evaluated the impact of decision aids on healthcare system. No statistical difference was found on overall cost, resource use, and provider and patient satisfaction. Results were mixed regarding changes in consultation length. Pooled results showed differences related to patient preference for less invasive options to surgery, but results of individual studies were mixed. The large heterogeneity, or differences between the studies, warrants caution when interpreting this outcome.

More detailed findings from this systematic review can be found in Appendix A.

Elsevier 2004

This systematic review of the uptake of prostate-specific antigen (PSA) testing following use of PtDAs included 7 decision aids and 11 evaluations (Evans, 2005). The meta-analysis showed the following:

- a) There was a significant reduction in probability of PSA testing after a decision aid (-3.5%; 95% CI 0.0 to 7.2%; $p = 0.050$;
- b) Improvements were gained in knowledge within two weeks after a decision aid (19.5%; 95% CI 14.2 to 24.8%; $p < 0.001$). The effect on knowledge was less pronounced within 12-18 months after a decision aid (3.4%; 95% CI -0.7 to 7.4%; $p = 0.10$).

American Society of Clinical Oncology 2007

This meta-analysis pooled the relative risk for 11 studies (randomized and non-randomized) designed to assess the effect of decision aids on the choice for surgery and knowledge of surgical therapy among women with early-stage breast cancer (Waljee et al, 2007). Results were mixed regarding patient preference for therapy, knowledge, and decisional conflict. More detailed findings from this study can be found in Appendix B.

Additional Studies

Quality of PtDAs

According to a systematic review regarding whether PtDAs meet IPDAS standards, 38 of 55 RCTs used at least one measure that mapped onto an IPDAS effectiveness criterion (O'Connor, 2007). According to the study, future trials need to use a minimum data set of IPDAS evaluation measures.

An earlier SR of PtDAs (Feldman-Stewart 2006) found that of 68 treatment PtDAs and 30 screening PtDAs identified, 17% of treatment PtDAs and 47% of screening PtDAs did not report any external consultation in their development. Content evaluations showed that treatment PtDAs frequently omit describing the procedure(s) involved in the treatment options. Additionally, screening PtDAs frequently focus on false positives (incorrectly saying that disease is present) but not false negatives (incorrectly saying that disease is not present). About 1/2 treatment PtDAs reported probabilities with a greater emphasis on potential benefits than harms. Similarly, screening PtDAs were more likely to provide false-positive than false-negative rates. An example from this systematic review was a decision aid for mammography that discussed the possibility and gave the probability that the test might inaccurately indicate breast cancer, but did not reflect the possibility or give the probability that the test might fail to detect the patient's breast cancer (Lewis, 2003). According to the authors of the systematic review, these results suggest that content within the decision aids frequently does not reflect balance and may not be including some information that would be critical to informed decision making.

Lack of Definition of Shared Decision Making

Much of the research to date has been done on the use of patient decision aids but does not address the extent to which a shared decision making process (which could include PtDAs, counseling, and other modalities) can affect patient decisions. According to one researcher (Makoul, 2006), the concept of SDM has been variably, and often loosely, defined. According to Makoul, this lack of synthesis is problematic for several reasons. First, inconsistent conceptual definitions lead to inconsistent measurement of SDM. Second, the lack of a core definition of SDM complicates efforts to identify the relationships between SDM and outcome measures. Third, variable instantiations of SDM definitions make comparisons across studies difficult, if not impossible.

Barriers and Facilitators to Use

Potential barriers to the use of patient decision aids include practitioner concerns about the PtDAs' comprehensiveness and up-to-datedness (Graham 2003). According to one study (O'Donnell, 2006), with the ever-shortening shelf life of scientific evidence, it is important that PtDA developers be closely linked to those who produce, summarize, and analyze evidence. Another potential barrier is lack of awareness of existing PtDAs for a particular clinical decision. While practitioners may agree with involving patients in health-related decisions, they do not always acquire the knowledge or skills to successfully practice shared decision making (Holmes-Rovner, 2000).

According to one researcher (O'Donnell, 2006), there is no evidence on the readability of decision aids and their suitability for particular audiences. Future research is required on how PtDAs work to improve decision quality for people who vary by demographic characteristics (age, sex, education, ethnicity) and baseline decision needs (stage of decision making, preference for participation in decision making) for better health outcomes.

Per O'Donnell (2006), the organizational culture can either hinder or facilitate the uptake of decision aids. In addition, structural barriers and pre-existing clinical care processes have all been cited as barriers in the uptake and/or appropriate timing of PtDA administration into the process of routine care.

A systematic review (Gravel, 2006) was performed on the barriers and facilitators to implementing shared decision making in clinical practice as perceived by health professionals. Thirty-one publications covering 28 unique studies were included. Overall, the vast majority of participants (n=2784) were physicians (89%). The three most often reported barriers were: time constraints (18/28), lack of applicability due to patient characteristics (12/28), and lack of applicability due to the clinical situation (12/28). The three most often reported facilitators were: provider motivation (15/28), positive impact on the clinical process (11/28), and positive impact on patient outcomes (10/28).

Conclusions and Recommendations

Discussion

While some results from the use of patient decision aids (PtDAs) and shared decision making (SDM) are encouraging, the vast majority of clinical trials involving PtDAs and SDM have not shown significant results. Findings tended to be strongest regarding increases in patient knowledge, but these gains diminished over time. Results were mixed regarding the effect of decision aids on patients' perceptions of their physical functioning, or attitudes toward their health status. While there was a significant, overall trend showing the influence of decision aids on patient preference for less-invasive surgical options, the large heterogeneity, or differences between the studies, warrants caution when interpreting this outcome.

Studies have indicated that most currently available decision aids do not meet international standards for quality. A lack of definition regarding shared decision making complicates its utilization in a clinical setting. Additional concerns include: challenges in keeping tools up-to-date, suitability of PtDAs for diverse populations, and challenges associated with organization culture. Facilitators to implementation include: provider motivation, positive impact on the clinical process, and positive impact on patient outcomes.

For decisions in health care that are preference sensitive, a shared decision making process can help patients to reach a decision that is both informed and aligned with their values. The literature shows that this field is still in development. More research is needed to advance the successful integration of shared decision making processes and tools beyond a research setting.

Policy Recommendations

The policy recommendations from HSAC to the Legislature are as follows:

Options Recommended

1. **Implement Pilot Studies** Develop pilot studies regarding the use of SDM in clinical settings. These studies should be conducted in a way that allows results from SDM and care within a health care home to be quantified independently. Issues to be addressed in pilot studies include, but are not limited to: 1) how to reliably identify and engage patients in SDM; 2) how best to provide decision support for different kinds of health decisions (e.g., preventive services, acute care, and chronic care); and 3) how or whether to compensate providers for these SDM services.
2. **Develop a Core Archetype of the SDM Process** Utilize the findings from pilot studies to develop a model for implementing SDM in clinical settings.

Options Not Recommended

3. **Mandate SDM** It is not recommended to mandate SDM. Mandating or requiring SDM as a condition of payment may create the perception by both patients and physicians as government interference in the physician-patient relationship. This may interfere dramatically with the adoption of SDM in clinical practice.
4. **Pay Providers for SDM** At this time, it is not recommended that providers be paid additionally for SDM activities. The literature does not show that SDM has an overall impact on cost and resource use in the clinic. While SDM is the type of activity that overall payment reform would recognize, fee-for-service payment specifically and separately for SDM is not recommended.
5. **Implement Payment Incentives Based on SDM Quality Measures** It is premature, in advance of successful pilot studies and the development of reliable measures of SDM quality, to implement payment incentives for adherence to SDM quality measures.
6. **Create a Legal Standing for use of SDM** It is not recommended that creation of a higher evidentiary standard for "failure to inform" malpractice law suits where SDM is utilized be implemented at this time. This model has been used in Washington State. However, any legislation on this should wait until after an analysis of the ramifications of modifying the Minnesota law is completed. The Minnesota Shared Decision Making Collaborative (MSDMC) is currently researching this option.

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Appendix A Cochrane Study Results

Patient Knowledge and Satisfaction

- a) **Difference Found:** These areas showed a significant difference between patients with and without PtDAs.
- Lower decisional conflict related to feeling uninformed (MD -8.3%; 95% CI -11.9 to -4.8) (10 trials);
 - Lower decisional conflict related to feeling unclear about personal values (MD -6.4%; 95% CI -10.0 to -2.7);
 - Reduced the proportion of people who were passive in decision making (RR 0.6; 95% CI 0.5 to 0.8);
 - Reduced the proportion of people who remained undecided post-intervention (RR 0.5; 95% CI 0.3 to 0.8).
 - Higher average knowledge scores (MD 15.2%; 95% CI 11.7 to 18.7) (18 studies);
 - When simpler decision aids were compared to more detailed decision aids, the detailed PtDAs were correlated with higher average knowledge scores (MD 4.6%; 95% CI 3.0 to 6.2) (9 studies);
 - Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions (RR 1.6; 95% CI 1.4 to 1.9). The effect was stronger when results were measured quantitatively (RR 1.8; 95% CI 1.4 to 2.3) (8 studies) than qualitatively (RR 1.3; 95% CI 1.1 to 1.5) (3 studies).
- b) **No Difference Found:** Decision aids were not statistically significantly associated with differences in these areas:
- State anxiety¹ (breast cancer – 2 studies; hypertension – 1 study; breast cancer – 10 studies; prenatal screening – 3 studies; pregnancy termination – 1 study; prostate cancer – 1 study; BPH – 1 study; HRT – 1 study; menorrhagia treatment – 1 study);
 - Decisional regret (1 study)
 - Trait anxiety² – prostate cancer treatment (1 study)

Health Care Quality and Costs

- a) **Difference Found:** Use of decision aids were statistically significantly associated with differences in these areas:
- PSA testing (RR 0.8; 95% CI 0.66 to 0.98; p = 0.03) (5 studies)
 - Use of Hepatitis B vaccination (*statistics not given*)
 - Use of menopausal hormones (RR 0.7; 95% CI 0.6 to 1.0, p = 0.04) (3 studies)
- b) **Indeterminate Findings:** Use of decision aids were associated with mixed results in these areas
- Complications of back pain - 1 study (back pain severity) found significant differences (p value not given); 5 studies (% working, % missed 1+ day within past month, leg pain severity, seeking compensation, and satisfied with symptoms) found no difference.
 - General health - 1 study (p = 0.02) found differences at baseline; no difference was found at 3, 6 and 12 month follow-ups.
 - Physical function 1 study (p = 0.02) found differences at baseline; no difference was found at 3 and 6 months follow-ups. Four other studies found no difference.
 - Role emotional – 1 study (p = 0.01) found a difference; one other study found no difference.
 - Role function - 1 study (p = 0.04) found a difference; two other studies found no difference.
 - Social function - 1 study (p = 0.02) found a difference at baseline; no difference was found at 3, 6 and 12 month follow-ups. Two other studies found no difference.

¹ State Anxiety: short-term anxiety in response to external stimuli.

² Trait Anxiety: long-term anxiety that is a relatively stable aspect of the personality.

- c) **No Difference Found:** Decision aids were not statistically significantly associated with differences in these areas:
- Adherence with the chosen option (warfarin versus aspirin, oral bisphosphonate medication, blood pressure medication, hormone replacement therapy)
 - Antithrombotic therapy for atrial fibrillation versus usual care
 - Preference for adjuvant chemotherapy for breast cancer
 - Uptake of pre-operative autologous blood donation
 - Uptake of medication for hypertension
 - Vaginal birth following previous cesarean section
 - Health outcomes
 - Angina (10 studies)
 - Bodily pain (3 studies)
 - Breast cancer genetic testing (4 studies)
 - Colon cancer screening (3 studies)
 - Depression (2 studies)
 - Energy (2 studies)
 - Functional status (1 study)
 - Health utilities³ (2 studies)
 - Menstrual symptoms (3 studies)
 - Mental function (3 studies)
 - SF-36 all dimensions⁴ (2 studies)
 - Urinary symptoms (4 studies)

Healthcare System Effects

- Four trials found no statistically significant impact of decision aids on overall cost and resource use;
- Changes in consultation length were inconsistent across studies;
- Patient and physician perception of the quality, usefulness and directiveness of the consultation session did not differ significantly when using PtDAs;
- Studies were pooled to determine whether use of PtDAs reduced the participant's stated preference to have surgery and/or reduced the number of surgeries that actually occurred. Eight studies evaluated the effect of PtDAs on a total of seven different major surgical interventions. Three of the eight studies had significant results regarding patient preference for less invasive treatment. These findings are shown below in Figure 1. According to the Cochrane review, overall results are significant for the pooled studies. Given the heterogeneity of the studies used in this analysis ($I^2 = 73\%$),⁵ these results should be interpreted with caution.

³ Health Utility Index: forms a single composite score based on self-reported status on eight attributes of functional ability.

⁴ SF-36: A survey of patient health with equal weight given to vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

⁵ Typically, I^2 values of 25%, 50% and 75% are considered low, moderate, and high levels of heterogeneity.

Figure 1A: Results from Cochrane 2009 – Patient Preference for Surgery versus Conservative Option. Intention to Treat Analysis.

	A	B	C	D	E	F	G	H	I
Intention to Treat	Decision Aid			Usual Care			Absolute Effect	Risk Ratio	Significance
	n	N	Event rate %	n	N	Event rate%			
Kennedy	83	300	27.7%	101	298	33.9%	-9%	0.78	
Morgan	45	120	37.5%	63	120	52.5%	-14%	0.79	P = .01
Murray	6	57	10.5%	1	55	1.8%	9%	5.33	
Vuorma	98	184	58.3%	88	179	49.2%	4%	1.08	
Bernstein	25	65	38.5%	28	53	52.8%	-17%	0.70	
Auvinen	60	104	57.7%	91	106	85.8%	-33%	0.64	P = .001
Barry	8	104	7.7%	16	123	13.0%	-6%	0.56	
Whelan	6	94	6.4%	26	107	24.3%	-18%	0.26	Not given
	330	1028		414	1041		-9%	0.75	95% CI 0.59, 0.94

Figure 1B: Results from Cochrane 2009 – Patient Preference for Surgery versus Conservative Option. As Treated Analysis.

	A	B	C	D	E	F	G	H	I
As Treated	Decision Aid			Usual Care			Absolute Effect	Risk Ratio	Significance
	n	N	Event rate %	n	N	Event rate%			
Kennedy	82	253	32.4%	101	244	41.4%	-9%	0.78	
Morgan	45	86	52.3%	63	95	66.3%	-14%	0.79	P = .06
Murray	6	54	11.1%	1	48	2.1%	9%	5.33	
Vuorma	98	184	53.3%	88	179	49.2%	4%	1.08	
Bernstein	25	61	41%	28	48	58.3%	-17%	0.70	
Auvinen	60	103	58.3%	91	100	91%	-33%	0.64	P = .19
Barry	8	103	7.8%	16	116	13.8%	-6%	0.56	
Whelan	6	94	6.4%	26	107	24.3%	-18%	0.26	P = .03
	330	938	35.2%	414	937	44.2%	-9%	0.75	95% CI 0.59, 0.94

Appendix B: Oncology Study Results

Final Treatment Decision

Two RCTs measured final treatment decision; one of these showed a statistically significant difference ($p < .05$) between treatment arms, favoring breast conserving surgery. The other RCT did not show a statistical difference. Two non-randomized trials measured final treatment decision; one was not significant, the other showed a statistically significant difference ($p < .05$) between treatment arms favoring mastectomy.

Knowledge

Seven studies assessed patient knowledge. Three studies (2 RCTs and 1 non-RCT) showed a significant increase in knowledge after use of a decision aid. Four studies (1 RCT and 3 non-RCTs) did not show a significant increase in knowledge.

Decisional Conflict

Four studies assessed differences in decisional conflict. One RCT and 1 non-RCT showed a significant difference ($p < 0.05$); 1 RCT and 1 non-RCT did not.

Convenience and Ease of Use

The report comments on convenience and ease of use but is unclear regarding the unit of analysis (patient or study) for the findings.

Attachment 1: Minnesota Shared Decision Making Collaborative

Shared Decision Making in Minnesota Policy Recommendations from the Minnesota Shared Decision Making Collaborative

Introduction

This report summarizes recent work on Shared Decision Making (SDM) in Minnesota and presents a set of recommendations regarding legislation to promote SDM in clinical practice. It was prepared by the Minnesota Shared Decision Making Collaborative (MSDMC) for the Health Services Advisory Council (HSAC) of the Minnesota Department of Human Services (DHS). HSAC is subject to a legislative requirement to deliver to the Minnesota legislature policy recommendations to promote SDM in Minnesota. These recommendations are due early in 2010. HSAC is reviewing possible legislative policy language in the fall of 2009. This report is intended to assist HSAC in its deliberations.

Executive Summary

The Minnesota Shared Decision Making Collaborative is a multi-stakeholder community learning collaborative working to promote the routine use of SDM in clinical practice throughout Minnesota. This collaborative currently benefits from the participation of staff from the Minnesota Department of Human Services, the Department of Health, and the University of Minnesota, as well as a wide variety of other organizations and individuals. Pilot SDM projects are underway at Stillwater Medical Group, Mayo Clinic, and HealthPartners Medical Group. The MSDMC is working to develop standardized approaches to defining, performing, and measuring SDM and decision quality.

As we proceed in this work we find that the evidence-base regarding SDM, particularly with respect to implementation in routine practice, is not yet mature; and there is much to learn. Significant questions remain about how best to help patients make complex medical decisions, how to implement SDM programs, and how SDM affects patient experience, service utilization, and health care costs.

To assist DHS in preparing SDM policy recommendations, the MSDMC convened a policy workgroup composed of a broad range of stakeholders. The workgroup reviewed recent Minnesota health plan experience requiring SDM as a condition of payment and found that requiring SDM had important negative unintended consequences. We also reviewed other state and federal SDM policy initiatives, and found that these efforts are developmental or early stage, and results are either non-existent or preliminary.

In formulating our recommendations, we considered a variety of policy options that we divided into three categories: 1) options that we recommend in the next two years; 2) options that require developmental work and are not recommended *at this time*; and 3) options that we do not recommend.

Options for the next two years

1. **Pilot studies** SDM pilot studies in clinical settings will help us learn more rapidly how best to provide this service. The health care home might be a good focus for an SDM pilot study focused on primary care services. Pilot studies provide a valuable opportunity to explore and identify the best approach to implementing SDM. Issues that need to be addressed in pilot studies include 1) how to reliably identify and engage patients in SDM; 2) how best to provide decision support for different kinds of health decisions (e.g., preventive services, acute care, and chronic care); and 3) how (or whether) to compensate providers for these services. Pilot studies may not require substantial resources, especially if they can be funded with research grants.
2. **Community education and social marketing** A state-wide campaign to raise awareness about the importance of practice pattern variation, patient preferences, and patient participation in medical decision making could add substantial value. We are eager to work with the State on such a project.

Options requiring developmental work

3. **Creating a legal incentive for SDM** Modifying Minnesota law to raise the level of evidence required for plaintiffs to prevail in a "failure-to-inform" malpractice suit when SDM was provided, while maintaining the current level of evidence required for informed consent, might help accelerate adoption of SDM. We are in the process of working with the legal community to determine how best

to effect this in Minnesota. Any legislation on this should wait until after developmental work has been completed.

4. **SDM decision quality measures** The MSDMC is working with Minnesota Community Measurement to develop valid and reliable measures of decision making quality. Once these measures have been shown to be robust and valid, state support in the form of DHS and SEGIP participation in pay-for-performance or other provider incentive programs based on these measures will support SDM adoption.

Options not recommended

5. **Mandated SDM** Mandating or requiring SDM as a condition of payment runs a high risk of being perceived by both patients and physicians as government interference in the physician-patient relationship. This may interfere dramatically with the adoption of SDM. We are also confident that through the collaborative process we will be able to implement SDM in Minnesota without legislative mandates, just as we have done with evidence-based medicine and patient safety.
6. **Paying providers for SDM** We believe it is too early to link SDM to fee-for-service (FFS) payment. For one thing, SDM may reduce provider resources required to perform effective patient education. In addition, pay-for-performance programs have succeeded in promoting evidence-based care and other clinical quality improvements, and may be effective for SDM. Finally, paying FFS for SDM may prematurely close off other promising approaches to provider compensation for SDM such as case rates, or total cost of care models.

A Brief History of SDM in Minnesota

HealthPartners Medical Group

In the 1990's HealthPartners Medical Group (HPMG, then Group Health) developed SDM programs in Urology and Ophthalmology. The programs were generally well received by patients but were difficult to sustain due to some physician resistance, and concerns about keeping the decision aids up-to-date.

More recently, HPMG has launched SDM pilot projects in four specialties: urology (prostate cancer), orthopedics (knee replacement), spine surgery (lumbar fusion), and breast surgery (early stage breast cancer).

Veterans Affairs Medical Center

A study published in 2004 by researchers at the Veterans Affairs Medical Center in Minneapolis compared two types of patient decision aids for prostate cancer treatment (a brochure vs. a video) and found that the decision aids were equally effective at increasing patient knowledge. [Partin, et al., 2004]

Mayo Clinic

Dr. Victor Montori at Mayo Clinic's Knowledge and Encounter Research Unit has been developing patient decision aids and studying SDM for chronic conditions. Recently he has been working to implement these methods in routine clinical practice at Mayo Clinic. [Carling 2009, Jones 2009, May 2009, Mullan 2009]

Stillwater Medical Group

Dr. Lawrence Morrissey, Medical Director for Quality at the Stillwater Medical Group, and researchers at HealthPartners evaluated the use of SDM for women with uterine fibroids. Their work demonstrated that measuring the quality of medical decisions, and implementing reliable patient decision support processes in clinical practice, are more difficult than expected; and many patients did not use the SDM materials or process fully. Unexpectedly, we found it difficult even to identify patients who were eligible for the study. [Solberg et al., 2009; Solberg et al., *in press*] The study intervention could not be sustained at HPMG; but Dr. Morrissey was able to maintain the SDM program at Stillwater Medical Group and has now expanded it to include SDM for patients making decisions about prostate cancer, breast cancer and benign prostatic hypertrophy. Stillwater is involved in a national clinical implementation collaborative sponsored by the Foundation for Informed Medical Decision making, and has new ongoing research projects on the implementation of SDM in primary care.

HealthPartners health plan

In 2004, HealthPartners health plan began a pilot SDM program in complex case management, under the leadership of Karen Kraemer, RN. Since then, this program has become a strategic initiative for reducing unwarranted variation in preference-sensitive care, and was expanded to other member-facing clinical services including nurse navigators and disease management nurses. These services have been well-received by

members and are associated with marked improvements in participant decision quality (knowing the risks and benefits of the options; knowing which risks and benefits matter most; and confidence in which option is best). Other health plans are also developing enhanced decision support programs. However, none of these programs engage more than a small minority of patients facing preference-sensitive health-related decisions.

Stratis Health

Stratis Health launched its Rural Palliative Care Initiative in 2008, and is working with 10 rural communities across the state to increase their capacity, knowledge, and skills in palliative care. A critical component in the initiative is improving goal setting and care planning, which involve use of shared decision making tools and approaches.

Minnesota Medical Association

In 2008, the Minnesota Medical Association adopted a resolution endorsing SDM and physician SDM training. This resolution was then adopted by the American Medical Association at its national convention.⁶ The AMA also endorsed SDM in an open letter to President Obama.⁷

Institute for Clinical Systems Improvement

In 2009, the Institute for Clinical Systems Improvement (ICSI) hosted several SDM educational programs, including an all day conference, a webinar, and presentations on SDM at the annual Spring ICSI Colloquium. ICSI is also incorporating SDM into their Palliative Care strategic initiative.

CentraCare

The Coborn Cancer Center at CentraCare in St. Cloud has developed an educational program called “Making Tough Decisions” for patients and members of the community. In addition to conducting these educational sessions on a monthly basis, they now receive frequent requests to give the presentation at the meetings of other community groups. These programs are well-received by patients, and could be the foundation of a more general, state-wide patient education campaign.

The Minnesota Shared Decision Making Collaborative

Given the low penetration of health plan decision support programs, it seems clear that SDM should be performed by the care delivery system as a routine part of care for preference-sensitive issues. To that end, in 2008 HealthPartners medical leadership, Dr. Larry Morrissey from the Stillwater Medical Group, Dr. Gary Oftedahl at ICSI, and Dr. Victor Montori at Mayo Clinic met to explore developing a community collaborative to promote state-wide adoption of SDM in clinical practice.

A steering committee was convened which included representatives from HealthPartners, Mayo Clinic, ICSI, Stillwater Medical Group, and the University of Minnesota Medical School Department of Family and Community Medicine. This steering committee hosted a half-day symposium on SDM in November, 2008. Approximately fifty health care leaders from across the state participated including patient representatives and representatives from a wide variety of organizations: the Minnesota Department of Human Services, the Minnesota Department of Health, ICSI, Minnesota Community Measurement, Stratis Health, Buyers Health Care Action Group (BHCAG), Fairview Health Services, Allina Hospitals and Clinics, Park Nicollet Health Services, HealthPartners Medical Group, Stillwater Medical Group, Raiter Clinic (Cloquet), Mayo Clinic, the University of Minnesota Medical School, the Veterans Affairs Medical Center in Minneapolis, HealthPartners health plan, Blue Cross and Blue Shield of Minnesota, Medica, Preferred One and UCare. The symposium featured presentations about SDM and variation in preference-sensitive care practice in Minnesota, and sought to answer the following questions:

- 1) Is unwarranted variation in preference-sensitive care an important quality problem in Minnesota?
- 2) If so, who cares, and why?
- 3) What should we do about it?

At the conclusion, the group consensus was that unwarranted variation in preference-sensitive care is an important quality problem; SDM is a promising strategy for addressing it; this work is especially important for patients and physicians; and while we don't know everything, we know enough to get started.

⁶<http://www.minnesotamedicine.com/PastIssues/December2008TableofContents/MMAnewsDecember2008/tabid/2760/Default.aspx>

⁷ <http://www.medicalnewstoday.com/articles/140573.php>

Following this meeting, the steering committee expanded its membership and formally re-convened as a learning collaborative called the Minnesota Shared Decision Making Collaborative. The MSDMC is not incorporated; it is a voluntary organization. As a consequence of this work, Minnesota is now viewed as a national leader in promoting SDM.

MSDMC Initiatives

Since its first meeting in December, 2008, the MSDMC has accomplished the following tasks:

- 1) Drafted a charter (submitted separately)
- 2) Defined “learning collaborative”
- 3) Initiated five workgroups:
 - a. The implementation workgroup is developing a template to be used by care delivery organizations implementing SDM programs
 - b. The measurement workgroup is developing a set of metrics to measure the SDM process and decision quality for quality improvement and for research
 - c. The shared lexicon workgroup is developing a set of definitions to foster standard, clear communication. The group is using a process called Paradigm Case Formulation to define SDM and decision quality, and to articulate how SDM differs from informed consent.
 - d. The media initiatives workgroup is developing a strategy to engage major Minnesota media organizations to include information about evidence-based medicine and preference-sensitive care in their coverage of health care
 - e. The SDM policy workgroup is developing recommendations regarding payer and policy initiatives for promoting SDM
- 4) HealthPartners funded the first statewide SDM Symposium and hosts MSDMC meetings. Steering committee and workgroup participants contribute their time *pro bono*. The MSDMC is seeking funding for additional administrative support to accelerate our work.

The SDM Policy Workgroup:

This workgroup includes representatives from patients, and payer and provider organizations, including HealthPartners health plan, Medica, BCBS of MN, UCare, Allina, Fairview, ICSI, Minnesota Medical Association, and DHS.

We have reviewed recent Minnesota experience linking SDM to provider payment or member benefits, and have found it to be problematic. Specifically in 2009, HealthPartners implemented a requirement that SDM be offered to patients as a condition of prior authorization for lumbar fusion surgery for degenerative disc disease. This policy led to some unintended consequences:

- Providers were unclear about the difference between informed consent and SDM. To the extent that they understood these differences, they were often unclear about how to implement decision support practices consistent with SDM.
- Health plan efforts to train providers were viewed as insufficient by some providers. In some cases, providers referred patients to health plan nurses, after a decision to operate had been made, for *pro forma* SDM, resulting in an unsatisfactory experience for both patient and nurse.
- There is some indication that the diagnosis codes for lumbar fusion surgery have migrated away from degenerative disc disease, thereby obviating provider compliance with this policy.

These consequences reveal that the provider community is not ready to operationalize SDM. There is confusion about what SDM is and why it matters. In addition, without adequate preparation, policies that mandate SDM are likely to have negative consequences for patients, cause avoidable conflict with physicians, and have the counterproductive effect of strongly associating SDM with cost cutting and “rationing” care. In contrast, the goal is to improve collaboration between patients and physicians, improve the quality of decision making, and reduce unwanted care. Government action requiring SDM may cause it to be perceived as unwarranted interference in the physician-patient relationship. This would greatly inhibit, if not destroy, the ability to achieve widespread adoption of this useful method.

Federal and State Legislation

The SDM policy work group's review of federal and state legislation regarding SDM was assisted by Ben Moulton, JD MPH, a member of the staff of the Foundation for Informed Medical Decision Making (FIMDM). Moulton was co-author of the 2006 article, "Rethinking Informed Consent: the Case for Shared Decision Making," published in *The American Journal of Law & Medicine*. [Staples-King and Moulton, 2006] The work group's findings were as follows:

1. **Maine:** legislation requires the Maine Quality Forum to convene an advisory group to develop a plan for implementation of SDM. A preliminary report is due February 1, 2010, and the final report is due February 1, 2011.
2. **Vermont:** legislation requires a plan for a SDM demonstration project by January 10, 2010. The legislation also requires a statewide analysis of variation in care focusing on preference- and supply-sensitive services.
3. **Washington:** legislation provides a higher level of malpractice protection when SDM is used. The legislation also authorizes a SDM pilot project.
4. **Federal—HELP Bill:** if passed, this authorizes funding for development and production of decision aids, provider education in their use and for shared decision making resource centers to provide technical assistance to providers. The bill authorizes the Secretary to contract with entities like the National Quality Forum to develop standards and a process of certification for decision aids, and SDM provider performance measures.
5. **Federal—Wyden-Gregg "Empowering Medicare Patient Choices Act":** authorizes a series of pilot programs to test SDM in primary care, specialty care and other settings. The implementation will have three phases: 1) three-year pilot with no more than 15 eligible providers considered "early adopters" with prior experience implementing SDM; 2) a second three-year pilot during which providers are eligible to receive reimbursement for using decision aids; 3) the final stage requires providers to use patient decision aids for preference-sensitive conditions as a standard of practice. The legislation authorizes The U.S. Department of Health and Human Services to provide financial assistance for the establishment and support of shared decision making resource centers.

All of these legislative initiatives, whether enacted or pending, are exploratory, developmental or facilitative in the short-term. The only legislation that would require providers to use SDM as a standard of care does so only after a six year period of development work. No results or outcomes are available yet from any of these initiatives.

Policy Recommendations

General comments: We share and heartily endorse legislative interest in promoting SDM; and we welcome policy initiatives that would facilitate the work of the MSDMC. However, our experience to date has made it quite clear to us (all passionate SDM advocates) that this field is "young." There are many unanswered questions about how best to provide patients with high-quality decision support, and how best to implement such programs in medical practices. We recommend legislative caution *at this time*, for two reasons:

- First, premature enforcement of SDM is likely to be counterproductive and may delay or prevent SDM adoption by patients and providers, despite the potential benefits to both.
- Second, there is now an active, community-wide multi-stakeholder group (the MSDMC) working to develop, implement, and evaluate SDM in medical practices throughout Minnesota. (Please see the MSDMC aims and goals in the Charter submitted separately.)

In the event that legislative or regulatory SDM policies are adopted, we recommend that they focus on facilitating this collaborative work rather than mandating or requiring SDM.

Below we review and make recommendations regarding the SDM-supportive policy approaches that the policy workgroup considered. For policies that might add value, we include a suggested timeline or sequence for adoption.

Pilot studies: Recommended

The second part of the Washington State SDM legislation authorized, but did not fund, a pilot study on the impact of SDM on utilization and cost of preference-sensitive services. Subsequently, Group Health of Puget

Sound, in collaboration with other Washington provider organizations, initiated a multi-year pilot study, funded by the Commonwealth Fund and with administrative support from the Washington State agency that manages state employee benefits. Interviews with Group Health Puget Sound staff indicate that they have successfully implemented processes for prescription and distribution of video decision aids and are now working to develop reliable and effective decision coaching capabilities that are necessary to achieve the full benefit of SDM. No published results from this pilot work are currently available.

Pilot studies provide an opportunity to explore how best to implement SDM and build the evidence base that will facilitate future broad-based adoption of this promising relational technology. Questions that need to be addressed in pilot studies include, but are not limited to:

1. How do we reliably identify and engage patients who are candidates for SDM during the process of care?
2. How do we best provide SDM (in various settings, for various types of decisions) so that patients make use of the service, and it is both efficient and effective?
3. Should we reimburse providers for SDM, and if so, how?
4. How do we train physicians and staff on SDM?

The pilot work at Stillwater Medical Group, Mayo Clinic, and HealthPartners Medical Group is beginning to provide preliminary answers to some of these questions; but much work remains to be done to create the evidence-base that would support wide-spread implementation of SDM as a standard part of care. Properly designed, state-funded or otherwise supported pilot studies of SDM in clinical settings will help us learn more rapidly how best to provide this service. Pilot studies need to be high quality so that they generate valid knowledge that can be quickly adopted in practice. The health care home might be a good focus for a SDM pilot study focused on primary care services. Pilot studies should be supported with sufficient resources to achieve the objectives noted above. High quality studies should be eligible for research funding which could defray a large proportion of the costs.

Community education and social marketing: recommended

A state-wide campaign to raise awareness about the importance of practice pattern variation, patient preferences, and patient participation in medical decision making could add substantial value. There is much to be learned about how best to speak about these issues with members of the public. Also, we believe there are some simple questions that patients can be encouraged to use that will allow them to shape their conversations with physicians so as to achieve a more shared decision-making experience. State support for these efforts is likely to be helpful; and we are eager to work with the State on such a project.

The MSDMC media initiatives work group has already begun to engage major media organizations in Minnesota in an effort to help journalists present well-balanced, evidence- and preference-sensitive health news stories. The CentraCare “Making Tough Decisions” patient education program suggests that there is substantial public demand for this sort of information. A patient-mediated “pull” approach could be a very effective way to promote adoption of SDM by providers.

Legislate public reporting of decision quality measures: not recommended at this time

There is a vibrant ongoing process in Minnesota for developing and implementing clinical practice quality measures. A representative of Minnesota Community Measurement (MNCM) is actively participating in the MSDMC and is co-leading the measurement work group. Once SDM measures are developed and piloted in medical practices, we plan to use existing provider performance measurement and reporting capabilities (MNCN and health plan), and existing provider recognition programs (Bridges to Excellence, and health plan pay-for-performance programs) to reward providers who have adopted SDM practices and to encourage others to join them. Both DHS and SEGIP participate in the BTE program. Until SDM measures have been developed and piloted, we do not recommend that they be subject to legislative or regulatory action.

Provider education and training mandates: not recommended at this time

The University of Minnesota, MMA, and Mayo Clinic are all participating in the MSDMC. MMA is publicly committed to promoting physician training on SDM. Pilot projects at Mayo Clinic, Stillwater Medical Group and HealthPartners Medical Group all involve provider training components. These efforts provide an opportunity to develop methods for educating and training physicians and other care delivery staff on SDM. HealthPartners Institute for Medical Education is planning another conference on SDM for the spring of 2010. We hope this will become an annual event. Continued participation of DHS and MDH staff in these activities

is welcome and much appreciated. However, we do not recommend that the legislature enact any medical education or training mandates at this time.

Enhanced legal protection for SDM: not recommended at this time

Washington State enacted a two-part law promoting SDM in 2007. The first part changed State law to require a higher standard of evidence for plaintiffs in “failure to inform” law suits when SDM had been provided. The new law maintains the requirement for “a preponderance of the evidence” for cases where the physician provided “informed consent” as defined in the Washington State law. For cases where the physician followed a SDM approach in addition to obtaining informed consent, the standard required is raised to “clear and convincing evidence.” This policy clearly creates an incentive for providers to adopt SDM, although the actual impact is not yet clear.

We think this policy approach is very promising, but work needs to be done to determine how best to effect it in Minnesota. If such a policy is adopted, it will be important that the legislation provide guidance as to how to distinguish between informed consent and SDM. Also, given the lack of evidence-based standardization of SDM processes, it is important that this guidance not be more prescriptive or detailed than is currently warranted.

Current work to develop a general definition of SDM in Minnesota, and specifically to make clear how it differs from informed consent, both conceptually and operationally, must be completed before it makes sense to legislate such a distinction in state law. The MSDMC is convening a group of malpractice attorneys to provide guidance on how Minnesota state law might best be enhanced to promote SDM. We recommend that any such legislation be delayed until after this definitional work has been completed. We expect to have the first phase of this work finished by mid-2010.

Mandate SDM: not recommended

Effective SDM is based on a relationship of mutual respect and trust, and requires that both parties to the process (patient and provider) engage in it willingly. Although most patients prefer to share in their medical decision making, not all patients prefer this role. These preferences need to be respected. Likewise, if providers do not willingly engage in SDM, they may undermine the process so that the desired benefits are not achieved. Finally, we fear that mandating SDM is likely to frame it as a government-imposed cost-cutting measure that interferes with the sanctity of the doctor-patient relationship, rather than a very useful technique for improving the doctor-patient relationship and medical decision making.

Make payment conditional on SDM: not recommended

In addition to the arguments above, making payment conditioned on SDM would require development of a manual claims process to identify and track use of SDM. This additional administrative burden may well add cost to the system.

Pay providers for SDM: not recommended

It is too early to conclude that provider organizations should be paid for SDM. For one thing, SDM might actually reduce patient education resource requirements for physicians. Several pilot studies indicate that properly implemented SDM actually reduces the time required for physicians to educate and help their patients make decisions. Also, there are many who believe that the main reason for doing SDM is ethical—it’s the right thing to do. As such, it is part of the physician’s fiduciary responsibility to the patient, and not something warranting extra compensation.

Finally, there are ongoing efforts in Minnesota to explore new approaches to provider compensation. These approaches include pay-for-performance, case management fees (such as used in the DIAMOND project), provider network tiering, and total-cost-of-care models. In the event that SDM requires the use of additional provider resources, one of these new models could be a better way to compensate providers for this work. In any case, we think this is a decision that is best decided by market forces. Prematurely legislating a fee-for-service approach could close off exploration of these promising alternatives.

Conclusions

SDM is a promising method of improving quality of care. Minnesota has a strong track record and a national reputation for improving health care quality, and improving unwarranted variation in evidence-based care. Preference-sensitive care is another quality improvement opportunity in Minnesota. SDM is a promising method for reducing unwarranted variation in patient preference-sensitive care and improving medical decision quality. The time is right for our community to tackle this issue.

Premature legislation could inhibit progress. The field is “young” and the evidence-base, especially regarding implementation, is not well-developed. Because of the collaborative leadership of both local providers and health plans, and the work of the Minnesota Shared Decision Making Collaborative, we are making real progress on SDM, and Minnesota is now perceived as a national leader in this area. Legislative and regulatory policies, appropriately timed, can foster this work and build on our momentum. However, premature or overly ambitious legislative action could inhibit progress or prevent exploration of important promising alternatives.

Payment should not be tied to SDM. At this time we recommend that no legislation be passed to mandate SDM or payment for SDM, or require it as a condition of payment. Once SDM quality measures have been developed and standardized, State program (DHS and SEGIP) participation in pay-for-performance programs using these quality measures will further support SDM adoption.

Enhanced legal protections could facilitate SDM in the future. Once the required definitional work to differentiate SDM from informed consent has been completed, a change in state law to provide a higher level of provider malpractice protection for SDM, while maintaining the current level of protection for informed consent, might help facilitate SDM adoption.

Community education and pilots would promote SDM. Likewise, legislative or regulatory action supporting SDM pilot projects and community education campaigns can help develop the SDM implementation evidence base and increase patient awareness and readiness to participate in SDM.

Methods to implement SDM should be developed. There is much work to be done to educate and train physicians on SDM; but first we need to develop the evidence base regarding the best methods of implementing this approach in practice.

Public-private collaboration. The Minnesota Shared Decision Making Collaborative is committed to promoting the widespread adoption of SDM in clinical practice. We look forward to actively working with our partners in the Minnesota State Government to achieve our shared goals of improving the quality of decision making for preference-sensitive health decisions and eliminating unwarranted variation in care.

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