Implementation of Shared Decision Making in Cardiovascular Care
Past, Present, and Future

Erik P. Hess, MD, MSc; Megan Coylewright, MD; Dominick L. Frosch, PhD; Nilay D. Shah, PhD

Despite recent health policy recommendations supporting shared decision making (SDM), a rapidly growing evidence base supporting the desirable effects of tools to facilitate SDM, availability of SDM tools specifically designed for cardiovascular care (Table 1),1 and recent advocacy for SDM in cardiovascular guidelines,2,3 SDM has not been widely incorporated into routine clinical practice. Although tools that summarize the best scientific evidence to support decision making, communicate risk, and prompt clarification of patients’ values and preferences may be necessary to support SDM, they are insufficient in and of themselves to routinize SDM. This lack of uptake of SDM may reflect many challenges associated with incorporating complex interventions into healthcare delivery. In this article, we describe the main approaches to SDM published in the literature to date, highlight barriers and facilitators relevant to each approach, and suggest future work that is needed to facilitate implementation of SDM in cardiovascular practice.

Approaches to SDM
Investigators have designed and tested patient decision aids that are delivered at different points along the continuum of medical care. Out-of-visit decision aids seek to activate and empower patients by informing them of their treatment options outside the context of the clinical encounter. One factor that influenced the development of out-of-visit approaches to SDM was data demonstrating regional variation in treatment driven, in part, by differences in physician preferences rather than the health status of patients.4 An example of one such decision aid is the Living with Coronary Heart Disease program developed by the Informed Medical Decisions Foundation.5 This decision aid helps patients with stable coronary heart disease distinguish between treatments that relieve symptoms (eg, angioplasty and stenting) and choices they can make to decrease their future risk of acute myocardial infarction (AMI), such as smoking cessation, exercise, and dietary changes. It also includes information about the pathophysiology of coronary heart disease and resources for understanding the available treatment options. The decision aid is available as a DVD, a booklet, and a web-based program. Health coaching, an augmented out-of-visit approach to SDM, has trained health coaches review materials with patients before the clinical encounter.6 This may better prepare patients to participate in decision making and enhance their ability to express their values and preferences.

In-visit decision aids are designed to be delivered by clinicians during the clinical encounter. One example of an in-visit decision aid is PCI Choice, a concise paper-based decision aid designed to guide patients with stable angina in decision making about percutaneous coronary intervention.7 The decision aid seeks to create a conversation between clinicians and their patients with stable angina about the potential benefits of percutaneous coronary intervention (ie, symptom relief) and clarifies the lack of reduction in the risk of death or AMI associated with coronary stents in this setting.8 The procedural risks associated with percutaneous coronary intervention and the likelihood that another revascularization procedure will be necessary in the next year are also quantified. Depending on whether an out-of-visit or in-visit approach is taken to facilitate SDM, different skills are needed to effectively deliver the decision aid, different implementation challenges are relevant, and different work is required to pave the path for implementation of SDM in practice. Although each of these approaches has its benefits, there is a dearth of research comparing the effectiveness of alternative modes of delivery of decision aids to enable decision making. It is possible that, depending on the nature of the decision, one approach may be preferable to another, and, in some cases, a combination of approaches may be synergistic and ideal. In addition, much of the research on the use of decision aids and SDM has taken a cross-sectional approach such that the effect of repeating SDM for decisions that need to be revisited is unknown. Similarly, approaches that may be focused on multiple decision-making encounters have not been tested (eg, first visit to review the evidence and a follow-up visit to make the decision). An overview of each
Factors Affecting Implementation of Out-of-Visit Approaches to SDM

There are several strengths and limitations to an out-of-visit approach to facilitate SDM. This approach is primarily relevant to elective treatment decisions in which patients have sufficient time to learn about their condition and the available treatment options. With acute conditions, such as new-onset chest pain that occurs unexpectedly and often prompts urgent medical evaluation, patients and caregivers typically do not have sufficient time to review their treatment options before the visit, necessitating use of an in-visit approach to SDM. That being said, there are several cardiovascular conditions in which there is sufficient time for patients to learn about their diagnosis and consider the available treatment options, such as whether to undergo coronary angiography in patients with stable angina, choice of anticoagulation therapy in patients with atrial fibrillation, or treatment choice for severe aortic stenosis.

Nearly, all the published studies of out-of-visit decision aids have used a referral model of implementation in which patients were either sent the decision aid by mail or directed to the decision aid at home by a healthcare professional. The referral model requires patients to be identified before a medical visit in which the condition of interest will be addressed by their clinician. Correctly identifying patients with a specific medical condition (e.g., aortic stenosis) based on a problem list is often feasible, although determining which visit clinicians address this with their patients has proven difficult. One study comparing different modes of decision aid delivery for preventative screening in colorectal cancer reported reaching the greatest number of decision aid eligible patients using an automated delivery method, but this resulted in 20% of the patients being inappropriately offered the intervention. One alternative may be to have patients review out-of-visit decision aids in the practice setting if the necessary space and equipment are available.

Other challenges that have been encountered when seeking to implement out-of-visit decision aids relate to clinicians’ pre-existing beliefs and concerns and logistical barriers (Table 2). Clinicians may not trust or agree with the content included in a decision aid or may not feel prepared to discuss the evidence patients have read in a decision aid without prior training. Clinicians may also think that patients do not want to take an active role in decision making and that patients prefer their clinicians to make decisions on their behalf without directly inquiring about the patient’s actual preference. This perception is in contrast to a recent survey of 6636 patients in the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status (TRIUMPH) and Prospective Registry Evaluating Myocardial Infarction: Events and Recovery Acute Myocardial Infarction (PREMIER AMI) registries, in which the majority (68%) of patients stated a preference for an active role in decision making and about a quarter (24.4%) preferred that the decision be theirs alone rather than shared with their clinician. A recent online survey of 1340 patients >40 years of age found that ≈70% preferred an SDM role in which patients and clinicians contributed equally to treatment decisions, and only 19% felt that the clinician should be mostly responsible for decisions. One reason that clinicians may perceive patients do not want an active role in decision making may relate to patients’ reluctance to disagree. Frosch et al. conducted a study of 6 focus groups of 48 well-educated, affluent patients from primary care practices in Palo Alto, CA. These investigators found that, despite having a strong desire to engage in decision making with their clinicians, patients felt compelled to defer to their clinicians during clinical consultations. The patients reported a fear of being categorized as difficult if they were to assert their preferences during a consultation and worried that this would put their future quality of care at risk. This study highlights a need for clinicians to set the stage by creating an open, safe environment for patients to ask questions, a need of which many clinicians may be unaware.

There are several logistical challenges to implement out-of-visit approaches to SDM as well (Table 2). Even if eligible patients are accurately identified before the encounter, office space and equipment to view videos or complex computer-based decision aids may not be feasible to obtain in smaller office-based practices. Additional logistical barriers to implement out-of-visit approaches to SDM identified in a recent study were time constraints, competing priorities, and lack of organizational support.

Clinicians have suggested potential solutions to increase the distribution and uptake of out-of-visit decision aids. These include the use of health coaches to provide decision support for patients, reminders within medical records, financial incentives, and including use of decision aids as a quality measure. Upstream communication by local physician leaders or quality improvement champions about the evidence selected for inclusion in a decision aid may increase clinicians’ confidence in the content. Training clinicians to create a safe environment for SDM, particularly among patients who have viewed an out-of-visit decision aid, may increase patients’ comfort in asking questions during the encounter. Educating clinicians about the evidence patients have read in a decision aid may also increase clinician’s comfort in engaging patients in decision making. SDM guidance reminders in practice, a system of practice tools and procedures that involves grand
Table 2. Beliefs, Concerns, and Logistical Barriers Likely to Be Encountered When Implementing SDM in Practice and Proposed Strategies to Overcome These Challenges

<table>
<thead>
<tr>
<th>Example of Potential Barrier</th>
<th>Relevant to Out-of-Visit Approach to SDM?</th>
<th>Relevant to In-Visit Approach to SDM?</th>
<th>Proposed Strategy to Overcome Challenge</th>
</tr>
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<tbody>
<tr>
<td><strong>Beliefs/concerns</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Clinician: “I already incorporate patients’ preferences in management decisions.”</td>
<td>✓</td>
<td>✓</td>
<td>Patients’ preferences are frequently misdiagnosed. In addition, patients’ preferences are frequently misinformed, may not be expressed for fear of offending their clinician and putting the quality of their future care at risk, and may change once properly informed.</td>
</tr>
<tr>
<td>Clinician: “My patients prefer me to make decisions on their behalf.”</td>
<td>✓</td>
<td>✓</td>
<td>In the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status (TRIUMPH) and Prospective Registry Evaluating Myocardial Infarction: Events and Recovery Acute Myocardial Infarction (PREMIER AMI) registries, 6636 (68%) patients preferred an active role in decision making, and nearly a quarter preferred that the decision be theirs alone rather than shared with their clinician. In an online survey of 1340 patients &gt;40 y, only 19% felt that clinicians should be mostly responsible for decisions. Patients’ reluctance to disagree may affect clinicians’ perception of patients’ willingness to engage in shared decision making.</td>
</tr>
<tr>
<td>Clinician: “I am not comfortable with the content included in the decision aid.”</td>
<td>✓</td>
<td>✓</td>
<td>Systematically selecting evidence for inclusion and engaging clinicians in an iterative development process may mitigate disagreement with the content included in the decision aid. When implementing the decision aid, clinical opinion leaders need to transparently communicate the sources of comparative effectiveness research evidence.</td>
</tr>
<tr>
<td>Clinician/Administrator/Payer: “What if doing SDM with patients decreases income for me and/or my practice?”</td>
<td>✓</td>
<td>✓</td>
<td>Policymakers need to propose approaches to payment reform, so loss of revenue is not a barrier to engaging patients in SDM. Another consideration is to include SDM as a component of performance metrics or other delivery system reforms such as accountable care organizations, the patient-centered medical home, and meaningful use of health information technology.</td>
</tr>
<tr>
<td>Patient: “I think my doctor will be offended if I ask questions and seek to participate in medical decisions. I am afraid of putting my future care at risk.”</td>
<td>✓</td>
<td></td>
<td>Clinicians may be unaware of the need to create a safe environment for patients to ask questions and participate in medical decision making and may not be trained to do so. In-visit approaches to SDM involve clinicians inviting patients to participate in the decision-making process, potentially mitigating patients’ fear of offending their clinician.</td>
</tr>
<tr>
<td>Patient: “I don’t understand my diagnosis or the available treatment options. How can I participate in decision making?”</td>
<td>✓</td>
<td></td>
<td>Health coaches can be made available as an option for patients seeking to better understand their medical condition and treatment options. To decrease information burden, use of concise in-visit decision aids may help patients focus only on information that is relevant to the decision at hand.</td>
</tr>
<tr>
<td>Clinician/patient: “I want to do SDM with my patients/doctor but am not sure how or where to start.”</td>
<td>✓</td>
<td>✓</td>
<td>It may be necessary to operationalize a comprehensive implementation program at the healthcare delivery system level to increase patients’ and clinicians’ comfort with SDM tools and approaches. The Shared Decision Making Guidance Reminders in Practice (SDM-GRIP) is an implementation program developed for stable coronary artery disease that has some evidence of feasibility.</td>
</tr>
<tr>
<td><strong>Logistical barriers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How do we consistently identify eligible patients before the visit?</td>
<td>✓</td>
<td></td>
<td>Data suggest that operationalizing an automated system that identifies patients who have a condition for which there is an applicable decision aid may have the greatest reach. However, automated systems will likely identify some patients who are not eligible for SDM, and this limitation should be taken into consideration.</td>
</tr>
<tr>
<td>Clinician: “I don’t have time to do SDM with patients in my busy practice.”</td>
<td>✓</td>
<td>✓</td>
<td>Engaging patients in SDM adds, on average, 3.5 min to clinical consultations. Much like the introduction of other process improvement interventions, there are competing priorities that vie for clinicians’ time, and interventions at the organizational and health policy level may be necessary for SDM to be prioritized over the status quo.</td>
</tr>
<tr>
<td>Clinician/administrator/other healthcare personnel: “Very few of the patients I refer to our pre-visit decision aids review the material before the visit.”</td>
<td></td>
<td>✓</td>
<td>Creating space within the clinic setting may enable patients to review decision aids before the visit. In addition, combining out-of-visit with in-visit approaches to SDM may increase the proportion of eligible patients exposed to decision aids, although this approach has yet to be tested.</td>
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PREMIER AMI indicates Prospective Registry Evaluating Myocardial Infarction; Events and Recovery Acute Myocardial Infarction; SDM, shared decision making; and TRIUMPH, Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients’ Health Status.
Table 3. Key Steps for Successful Implementation of SDM

<table>
<thead>
<tr>
<th>Key Issues Around Successful Implementation of SDM</th>
<th>Example: SDM Around Statins in the Clinical Encounter (Statin Choice)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buy-in at the practice level to implement SDM and an understanding of how this would</td>
<td>Belief in the value of engaging patients in decision making and an</td>
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<tr>
<td>change the interaction with patients</td>
<td>understanding that it results in different types of discussions</td>
</tr>
<tr>
<td>Willingness to change one’s practice at the individual clinician level</td>
<td>An appreciation of the potential for risk-tailored medication</td>
</tr>
<tr>
<td>Designing the workflow to fit the practice and engaging key participants in the design</td>
<td>The article-based Statin Choice requires risk calculation of each</td>
</tr>
<tr>
<td>process</td>
<td>individual patient and easy access to the appropriate version of the</td>
</tr>
<tr>
<td>Reassessing and redesigning the workflow</td>
<td>decision aid. This may require ready access to the article-based risk</td>
</tr>
<tr>
<td>Evaluating the effect of the intervention on the practice</td>
<td>risk calculator at the desk of the clinician, the decision aid is</td>
</tr>
</tbody>
</table>

SDM indicates shared decision making.
surgical intervention decreased from 75% to 58% (95% confidence interval for the difference, 4%–31%) after exposure to the decision aid. These considerations suggest that there may be gaps between the preferences clinicians perceive patients have and the preferences patients actually hold and that those preferences may change once patients are properly informed of the treatment options.

Several facilitators of in-visit approaches to SDM may mitigate against the barriers described previously. The following suggestions are a result of in-depth qualitative interviews of clinicians who used 3 of the in-visit decision aids that were developed at Mayo Clinic and tested in trials. First, enthusiasm for the decision aids frequently revolved around risk quantification. Clinicians expressed the belief that risk communication is a core aspect of their job, and a decision aid with individualized risk estimates generated from a validated risk instrument helped them engage more authoritatively in discussions with their patients.

Next, clinicians reported that the structured design of the in-visit decision aids helped guide their discussion with patients, although reassurance that the aids were designed to be flexible in their delivery was needed to facilitate clinician comfort with the tools. When orienting clinicians in the context of our trials, a 1-hour grand rounds presentation in which the principal investigator demonstrated the use of the tool followed by a brief 2- to 3-minute refresher at the time of patient enrollment by a study coordinator has been sufficient training for clinicians to engage in SDM during the encounter. Given cardiologists’ trust of professional society guidelines, inclusion of SDM in guidelines may also increase clinicians’ willingness to engage patients in decision making.

Implementing SDM Interventions in Cardiovascular Practice: A Way Forward

Thus far, we have primarily discussed approaches to mitigating clinicians’ pre-existing beliefs and concerns about SDM. In summary, the key aspects of initial clinician engagement include awareness by clinicians of patients’ reluctance to disagree, their own misdiagnosis of patients’ preferences and health beliefs unless they are specifically elicited, an appreciation that patients’ preferences may change once informed, and the need to create a safe environment for patients to feel comfortable engaging in healthcare decisions. At this stage, clinicians may be motivated to gain experience with decision aids they find compelling. Thus, the next step involves increasing awareness of and addressing logistical barriers to implementation.

Logistical challenges to out-of-visit SDM may be partially overcome if healthcare delivery system leadership believes in the value of SDM and allocates the resources needed to do so. Group Health, a health system that provides medical care and insurance to >600,000 residents of Washington State and Idaho, is one such organization and has reported the effect of distributing previst decision aids across their health system as part of a quality improvement initiative. In January 2009, a multidisciplinary SDM implementation team consisting of clinicians and executive leaders introduced an evidence-based video and written decision aids on hip and knee osteoarthritis. All orthopedic staff were required to watch videos of both decision aids and to attend planning meetings, and clinical leaders encouraged clinicians to distribute the decision aids to all patients with the conditions of interest. Although the investigators were not able to accurately confirm the proportion of patients who viewed the decision aids before the encounter, they observed 26% fewer hip replacement surgeries, 38% fewer knee replacements, and 12% to 21% lower costs during the 6-month follow-up period. Because the authors could not actually validate the actual viewing of the decision aid, one cannot tie the lower use and costs to the use of decision aids, especially because this study was conducted during the recession, and there is evidence that individuals were deferring such procedures during this time period. In addition, individuals who received hip and knee surgery decision aids during the intervention period had higher hip and knee replacement rates compared with controls in the 180 days after receiving the decision aids.

Frameworks such as the normalization process theory can also be used to enable successful implementation of complex interventions such as SDM. The core constructs of normalisation process theory include coherence, cognitive participation, collective action, and reflexive monitoring. Coherence is the sense-making that the individual and the group have to undertake to operationalize SDM. Cognitive participation is the understanding of the work that is needed to undertake to implement the intervention. Collective action is the actual work that is needed of each individual to successfully implement SDM. Reflexive monitoring is the appraisal that individuals and the group do to assess the value of SDM after implementation. These constructs have been applied in the context of SDM in Table 3. We have used the example of Statin Choice, an in-visit decision aid designed to engage patients in the decision of whether to start taking a statin, to highlight the types of issues that would be necessary to address for successful implementation of an in-visit decision aid.

Changes in health policy have been and will continue to be important to facilitate implementation of SDM in clinical care. One key factor that set the stage for the quality improvement effort at Group Health was legislation in Washington State that supported decision aids and SDM processes as a higher standard of informed consent. Several states have adopted similar legislation, and law supporting the development of standards for the certification of patient decision aids, SDM resource centers, and funding to support further research in SDM was included in Bill H.R. 3590 Section 936 of the Patient Protection and Affordable Care Act. Additional policy changes that may further encourage adoption of SDM include liability protection for clinicians, payment reform supporting SDM efforts, and including SDM as a key component of delivery system reforms, such as the patient-centered medical home, accountable care organizations, and meaningful use of health information technology. Another key concern for policy changes is that they be implemented in such a way as to encourage meaningful SDM and avoid the pitfalls of a check-box mentality as has occurred with other ineffective performance measures.

Given the strengths and limitations of out-of-visit and in-visit approaches to SDM, one might hypothesize that a combination of the 2 approaches might be more efficacious.
than either alone. One way of conceptualizing these respective approaches is to consider out-of-visit approaches as creating a patient push and in-visit approaches as creating a physician pull. Although an SDM approach including both push and pull characteristics is conceivable, we are aware of no SDM tools that include both elements and studies that demonstrate the effect of combining both approaches. This is one fertile area for future research.

We also recommend that key elements as described in the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines38 (eg, physical resources, organizational culture, history of change efforts, the structures and patterns of care that provide context for the intervention, and sequence of steps, events, or phases) be reported in future SDM implementation studies. Steps taken to encourage implementation at the clinician level (eg, addressing pre-existing beliefs and concerns, training in SDM, and use of SDM tools), patient level (eg, key aspects of tools developed for patients), system level (eg, steps taken to address logistical challenges in care delivery, development of systems to systematically identify eligible patients), and health policy level (eg, performance metrics, payment reform) should be described in sufficient detail to permit replication. Transparent reporting of these data elements will help others accurately interpret the effectiveness of implementation efforts, replicate those efforts in other contexts, and effectively advance the science of SDM implementation.

Although there are several challenges that exist for a clinician to incorporate SDM in clinical practice, there are ways to take the existing evidence and tools and use them routinely. A first pass is to identify sources of decision-making tools that may be routinely available, especially for a topic of interest to the clinician. Three excellent sources can serve as a starting point to access publicly available tools (among others). These include the Ottawa Decision Aids Repository (available at http://decisionaid.ohri.ca/AZinvent.php), the Mayo Shared Decision Making Resource Center (available at http://shareddecisions.mayoclinic.org/), and a repository of Option Grids (available at http://www.optiongrid.org/). Each of these sources has tools that may be downloaded for immediate use either in paper form or electronically. Once the clinician has identified a source that has synthesized the evidence, it would be important to consider where in the routine clinical workflow the tools would work best. This may differ by the nature of the decision, as well as the type of materials that may be available (out-of-visit or in-visit materials). Once the best flow for implementing the decision aid has been identified, the clinician can test this model and iterate the best flow to enhance decision making.

Conclusions

Several factors have contributed to a recent increased focus on SDM in health care, including changes in health policy, new opportunities for research funding through the Patient-Centered Outcomes Research Institute, advancement of the scientific knowledge base supporting the efficacy of patient decision aids, development of several decision aids specific to cardiovascular care, and incorporation of SDM in recent cardiovascular guidelines. Decision aids are tools that educate and prepare patients to engage with their clinicians in SDM, and both out-of-visit and in-visit decision aids have been used to facilitate SDM. Each of these approaches has unique strengths and limitations, and different skills and resources are required to implement them in practice. Several strategies may help mitigate the challenges one will encounter when implementing SDM, and these can be applied at the patient, clinician, healthcare delivery system, and health policy level. Future implementation work is needed to gain greater insight and to more effectively implement SDM in cardiovascular practice.

Disclosures

Dr Frosch has served as a paid consultant for the Informed Medical Decisions Foundation. The other authors report no conflicts.

References


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