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), and recent advocacy for SDM in cardiovascular guidelines, 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. An example of one such decision aid is the Living with Coronary Heart Disease program developed by the Informed Medical Decisions Foundation. 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. 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. 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. 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
of the approaches to SDM that have been addressed in the literature to date is presented below.

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 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. 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.

Table 1. Decision Aids to Facilitate Decision Making for Cardiovascular Conditions: Publicly Available Through the Ottawa Health Research Institute

<table>
<thead>
<tr>
<th>Condition</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute chest pain (1)</td>
<td></td>
</tr>
<tr>
<td>Arrhythmias (8)</td>
<td></td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation (1)</td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure (2)</td>
<td></td>
</tr>
<tr>
<td>Coronary heart disease (7)</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia (3)</td>
<td></td>
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<tr>
<td>Hypertension (4)</td>
<td></td>
</tr>
<tr>
<td>Peripheral artery disease (1)</td>
<td></td>
</tr>
<tr>
<td>Stroke (3)</td>
<td></td>
</tr>
<tr>
<td>Valvular heart disease (2)</td>
<td></td>
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</tbody>
</table>

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
Beliefs/concerns

<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>
</thead>
<tbody>
<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>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>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 don’t understand my diagnosis or the available treatment options. How can I participate in decision making?”</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-vist 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>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>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>
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Logistical barriers

<table>
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<th>Example of Potential Barrier</th>
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<th>Proposed Strategy to Overcome Challenge</th>
</tr>
</thead>
<tbody>
<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>
</tr>
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Factors Affecting Implementation of In-Visit Approaches to SDM

An alternative approach is 1 in which the clinician initiates SDM during the clinical encounter using brief decision aids to facilitate a conversation about the treatment options, the pros and cons of each option, and identifying which option aligns most closely with patients’ values and preferences. Although an in-visit approach to SDM has several strengths, the most notable of which is that clinicians have the opportunity to invite patients to enter into a dialogue and create a safe environment for patients to engage in decision making, there are several limitations as well (Table 3). If patients are not familiar with their diagnosis and treatment options before the visit, a substantial proportion of the dialogue must be devoted to patient education before an informed decision can be made, requiring clinicians to allocate limited visit time to education. This can be challenging, particularly for patients with complex health decisions, lower health literacy, or those who are non–English speaking. Furthermore, educating patients to prepare them for SDM may not be of sufficient priority for the clinician, particularly if there are financial incentives or time constraints that prioritize efficiency over communication. Clinicians may not feel that a decision aid applies to a patient, given the clinical scenario or other factors unique to that patient. To overcome some of these challenges, it is critical to undertake a user-centered approach when developing these decision aids by engaging both patients and clinicians in an iterative design process.25

Clinicians may also be reluctant to engage patients in SDM if they think that a particular treatment option is strongly preferred or, stated another way, there is no uncertainty associated with the decision. However, decision aids can be used not only to engage patients in decision making but also to enhance knowledge transfer to patients about the risks and benefits of the options. This knowledge transfer may be beneficial in cases where a treatment option is favored, but patient action is required. Patients having this additional knowledge may not only be nudged toward the preferred decision but may also follow through on the required action. In a decision aid that was developed to facilitate a discussion in hospitalized post-AMI patients about their medication options, AMI Choice, cardiologists were reluctant to offer patients a choice because the medications were shown to have mortality benefit and recommended by treatment guidelines. This reluctance to engage patients in SDM existed despite evidence demonstrating adherence rates of only 50% within 2-year post-AMI29 and data suggesting that SDM might improve medication adherence.30 In this case, one of the main goals of the decision aid is to transfer individualized benefit and risks to the patients to enhance medication adherence.

Clinicians may think that they already incorporate patient preferences into management decisions. In a survey of patients with breast cancer and their treatment providers, clinicians thought that 71% of patients rated keeping their breast as a top priority, whereas only 7% of patients rated breast conservation as their top priority,18 suggesting that clinicians frequently misdiagnose patient preferences.19 In a survey of 207 patients and 29 primary care clinicians, clinicians overestimated the frequency with which patients attributed their medical illness to a biological cause rather than something they can control, suggesting that clinicians incorrectly perceive patients’ health beliefs.31 Data are strong within cardiology that clinicians are not as effective in educating and engaging patients as they perceive. For example, in one study, ≈90% of patients with stable angina thought that undergoing percutaneous coronary intervention would decrease their risk of heart attack despite having met with a cardiologist previously.4,20 In addition, once patients are properly informed of the risks and benefits of treatment, their treatment preferences may change. In a randomized trial of a decision aid for patients with stable angina conducted in Canada, the proportion of patients who opted for

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>
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<tbody>
<tr>
<td>Buy-in at the practice level to implement SDM and an understanding of how this would change the interaction with patients</td>
<td>Belief in the value of engaging patients in decision making and an understanding that it results in different types of discussions around initiating statins are both necessary.</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 treatment decisions and the improved adherence to treatment that may result is necessary for individual clinicians to be willing to take on the additional work required to incorporate shared decision making.</td>
</tr>
<tr>
<td>Designing the workflow to fit the practice and engaging key participants in the design process</td>
<td>The article-based Statin Choice requires risk calculation of each individual patient and easy access to the appropriate version of the decision aid. This may require ready access to the article-based risk calculator at the desk of the clinician, the decision aids to be stocked within the office and supplies to be maintained.</td>
</tr>
<tr>
<td>Reassessing and redesigning the workflow</td>
<td>Our assessment showed that incorporating the tool into the electronic medical record and automatic calculation of individual patient’s risk within the electronic medical record would significantly streamline the process and incorporate greater individualization of the decision aid.</td>
</tr>
<tr>
<td>Evaluating the effect of the intervention on the practice</td>
<td>At the end of a 6-mo period, assess patients’ experience, the degree of concordance between risk and treatment, and adherence to treatment.</td>
</tr>
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</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.21 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.25,26 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. 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.25,26 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.

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 >660,000 residents of Washington State and Idaho, is one such organization and has reported the effect of distributing previsit decision aids across their health system as part of a quality improvement initiative.33 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.34 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 normalization process theory include coherence, cognitive participation, collective action, and reflexive monitoring.34 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.35 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.36 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.37

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.oahp.ca/decisionaid.html), 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

Implementation of SDM in Practice


KEY WORDS: acute coronary syndrome • atrial fibrillation • decision making • myocardial infarction
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