Dr Jones is a 55-year-old surgeon with class I angina. Her exercise stress echocardiogram shows mild ischemia involving 2 segments of the inferior wall, and diagnostic coronary angiography demonstrates a right coronary artery discrete, mid-80% stenosis. She is meeting with her cardiologist to decide whether to pursue percutaneous coronary intervention (PCI) with a drug-eluting stent or continue her current medications (aspirin, atorvastatin, metoprolol, and nitrates). Current research evidence suggests that PCI and medical therapy have comparable outcomes for death and myocardial infarction, as well as similar relief of angina symptoms at 1-year follow-up. PCI might achieve more rapid relief of symptoms but with some risk for bleeding, stent thrombosis, and restenosis. This risk is not present with medications; however, these might take longer to titrate and achieve improvement of symptoms and have their own potential side effects.2,3 How should Dr Jones, the patient, decide between PCI and medical therapy?

Spatz and Spertus4 have described the primary challenge facing American health care in the 21st century as the need to improve evidence-based, cost-effective, and patient-centered care. Although healthcare organizations and clinicians study, measure, and improve gaps in evidence-based and cost-effective care, patient-centered care lacks comparable science and action. Spatz and Spertus4 have proposed shared decision making (SDM) as the path forward to achieve patient-centered care and have introduced a series of articles in *Circulation: Cardiovascular Quality and Outcomes* to describe the state of the science in SDM, design and test tools for SDM, implement SDM in clinical practice, understand measurement and outcomes of SDM, and promote policy and accountability in SDM. In this introductory article, we address the following questions:

1. Why do we need SDM?
2. How should we do SDM?
3. How should we measure SDM?
4. How should we promote SDM?
5. What are the future directions of SDM?

**Why Do We Need SDM?**

Evidence-based medicine requires an explicit process in which clinicians determine the available options and the likelihood these will lead to favorable and unfavorable outcomes. This process involves 2 judgments. The first judgment concerns our confidence in the estimates of treatment effect across the outcomes that matter most to patients.2 This confidence is high when those estimates are produced by unbiased, precise, consistent, fully reported, and directly applicable randomized trials. The second judgment is to determine which treatment best fits the patient’s context, goals, values, and preferences.6 Both judgments require clinical expertise and experience, but the second mandates patient expertise and experience. Thus, the full realization of evidence-based medicine necessitates the participation of both patients and clinicians in making decisions, a process called SDM. We need SDM to practice evidence-based medicine.

Cardiovascular medicine has promoted evidence-based medicine by developing clinical practice guidelines, performance measures, and appropriate use criteria for common cardiovascular diseases and procedures.7-9 How does patient involvement and SDM fit with this context? Dr Jones’ dilemma highlighted in the clinical case, choosing between PCI and medical therapy for stable angina, is an opportunity for SDM.10 SDM is particularly relevant for Class Ia or Iib guideline recommendations, where patients and clinicians are faced with alternative treatment options with comparable outcomes or where one option might have modest benefit compared with the alternative. There are widespread examples in cardiovascular medicine, such as use of implantable defibrillator for primary prevention of sudden cardiac death,11 transcatheter or surgical aortic valve replacement for aortic stenosis,12 and carotid stent or carotid endarterectomy for carotid stenosis.13 Failure to involve patient choice results in a decision based on clinician goals, values, and preferences, in turn leading to patients receiving a treatment they might not have chosen if they knew what clinicians know and had the opportunity to voice their preferences. This situation is analogous to a diagnostic error, an incorrect diagnosis of patient preferences.14 To avoid misdiagnosis of preferences in the case of Dr Jones, the clinician must involve her in deliberation about the option of PCI versus medical therapy. To do so, her clinician must not only invite Dr Jones to consider the options together but should share evidence-based information that leads to more realistic patient expectations about these options. Rothberg and colleagues15 recently
documented that >75% of patients who had undergone PCI believed that PCI would reduce mortality or their risk for myocardial infarction. These patient preferences could be markedly different if patients were informed that PCI conferred no benefit for mortality or myocardial infarction as compared with medical therapy.

A few recommendations in cardiology are strong (Class I, Level of Evidence A).16 For these, SDM is relevant especially if the recommended treatments require changes in patient lifestyle, behavior, and action to implement and sustain the decision and achieve the desired outcomes. For example, β-blockers and statins are Class I recommendations for patients hospitalized with acute myocardial infarction,17 and clinicians prescribe these medications for ≥90% of patients at the time of hospital discharge for those without contraindications.18 However, many studies have demonstrated that adherence to these evidence-based medications declines to ≤50% at 1-year follow-up.19,20 This observation suggests that patients either do not understand the benefit to continue taking these medications or do understand the benefit but choose to stop taking these medications. Without involving patients in this decision, it should not be surprising that patients will prematurely discontinue life-saving medications.

At least in part, this lack of patient involvement also suggests that clinicians overlook the unique challenges patients might face in implementing and sustaining the recommendation. Anticoagulation with warfarin in patients with atrial fibrillation is another Class I recommendation. This recommendation assumes a certain balance of risk and benefit, which requires patients to adhere to the medicine, a diet, and regular monitoring. Patients might understand at the time of prescription how likely they are to be able to adhere to these behaviors and, thanks to their participation in decision making, identify whether this or an alternative is best. Thus, another justification for SDM is to ensure that patients realize the value of effective interventions through their implementation with high fidelity.

In summary, patients are the best experts about their context, goals, values, and preferences for health care. Their participation in decision making helps clinicians make informed judgments about how to translate the research evidence into practice and improve the fit between the management plan and the patient who will implement it and live with its intended and unintended consequences. Also, SDM might improve patient fidelity to the mutually agreed plan and improve safety by reducing the misdiagnosis of patient preferences. These practical justifications extend the well-rehearsed ethical justification for SDM based on the principle of autonomy that patients should be empowered to make informed decisions regardless of implications for cost, clinical performance measures, and clinician time and effort.21,22

To these ethical and practical justifications, some add the ability of SDM to reduce healthcare costs and overuse of invasive procedures.23 These justifications, not supported by the evidence, are actually subordinated to the ethical and practical justifications we noted before. That is, when SDM does not result in reductions in cost or healthcare utilization, the practice of SDM is still ethically good and a marker of high-quality care.

Policymakers have recently included provisions in the Patient Protection and Affordable Care Act to reimburse SDM [bill H.R. 2590 (IIITH)], and some states (such as Washington and Minnesota) have enacted legislation for SDM.24 Organizations, including the Institute of Medicine25 and the Patient-centered Outcomes Research Institute,26 have also promoted programs and funded studies for SDM, respectively. Professional societies, including the American College of Cardiology (ACC) and American Heart Association (AHA), have recommended SDM in their clinical practice guidelines for PCI,27 congestive heart failure,28 and atrial fibrillation.29 Recently, 11 chief executive officers of leading healthcare systems proposed a Checklist for High Value Healthcare, which included SDM as one of the key strategies to simultaneously improve outcomes and reduce costs.30 The legislative and healthcare organizational attention to SDM seems focused on its ability to reduce costs.

In an era when healthcare is rapidly transforming to achieve the triple aim of better patient care and experience, better population health, and more affordable care, SDM plays a critical role to promote patient-centered care. SDM should not be viewed as a strategy to decrease cost by directing patients to choose the least expensive treatment or reduce variation in care by mitigating decisions driven by clinician preference. This, no matter how laudable, will require manipulation of the patient with irreparable loss of trust. Costs, we must remember, is not an ends outcome; it is a means outcome. The end here is better patient health mediated by better patient and clinician engagement in decision making.

**How Should We Do SDM?**

In practice, clinicians strive to be empathetic and expert and to help patients make medical decisions for medications, tests, procedures, and strategies for care often with the framing, “If I were you, then this is what I would decide to do” or “If you were my family or relative, this is what I would recommend for you.” This framing makes 2 important assumptions: (1) the clinician knows the patient’s social context such as their family, job, and other responsibilities; and (2) the clinician knows the patient’s goals, values, and preferences for their health. In the current era, it is unlikely that clinicians, often having little in common with their patient in terms of social context, community, or education, will accurately acquire, guess, or incorporate this information during the typical clinical encounter lasting 15 to 45 minutes.

Alternatively, what if clinicians framed the medical decision to, “What would the patient decide if the patient had my knowledge, expertise, and experience?” This framing assumes that the clinician’s knowledge, expertise, and experience can be transferred and understood by the patient. Analogous to the flipped classroom model for education,20 the clinical encounter is transformed to an opportunity for the patient to ask questions and achieve greater clarity concerning the benefits and risks between alternatives or no treatment. Finally, a third way to frame the medical decision would be to use a trusted agent or health coach who understands the patient context and preferences, as well as the research evidence, and functions to coach the patient to make the best decision. The latter 2 approaches are the most aligned with the overarching
How Should We Measure SDM?

SDM requires patient involvement in decision making. For patients and clinicians to be on the same page, they need to share and communicate information. A key outcome of SDM is knowledge transfer of the benefits and risks of alternative treatment options. If successful, patients report feeling informed and able to make decisions that reflect their goals and values and that they can do so free of any pressure, a concept sometimes described as decisional comfort or, in a negative frame, decisional conflict. But these, along with patient and clinician satisfaction, the actual choice, and clinical and financial outcomes, represent downstream results of the decision-making process. The most important measures of SDM are those that capture the extent to which SDM actually took place. There are multiple challenges to measuring the quality of the decision-making processes. These include inaccurate and incongruent patient and clinician accounts, inaccurate documentation of what took place in the encounter, lack of validated instruments, and reliance of recordings of the encounter for third-party judgments of unclear validity. With the introduction of more and better tools for SDM, it will be equally important to demonstrate that these tools have efficacy to enhance knowledge transfer, decisional comfort, and patient engagement. Furthermore, measurement is also needed to assess the effectiveness of implementation of validated SDM tools.

How Should We Promote SDM?

Although there may be general consensus on the need, rationale, and goals for SDM, challenges remain concerning the best approaches for how to promote SDM in clinical practice. SDM should not be reduced to a mandatory activity such as documenting informed consent or filling out a checklist. Studies have shown that informed consent has become the minimal floor for communicating risks and benefits, confusing a much-needed process for patient engagement with the completion of a document. Many patients do not read this document or understand that alternatives or no treatment are viable options. Furthermore, SDM should not be implemented as a printout or an electronic checklist to document that a decision aid was given to the patient. Such mandatory activities have resulted in medication prescriptions that are never filled or education materials that are never reviewed.

What if we considered SDM as vital as performing a history and physical examination or conveying empathy, trust, and hope to provide health care? In this framing, performing the physical examination and conveying trust are not mandated by or undertaken to comply with external requirements and not subject to public reporting or financial incentives. Rather, SDM becomes a core function of the clinician’s professional responsibility. Such positioning is consistent with the justifications of SDM on the grounds of ethics and patient-centered care. By viewing SDM as our professional responsibility, rather than as mandated by internal or external regulatory requirements, SDM will be better positioned to achieve the ultimate goal of patient engagement and patient-centered care.

What Are the Future Directions for SDM?

The future of SDM is a new scientific field where much work remains to define the appropriate methods to measure process and outcomes of SDM, design and test tools to facilitate SDM, understand the barriers to implement SDM in clinical practice, and promote policy and accountability in SDM. Future research should inform what type of problems can be solved with SDM. What is the role for SDM to mitigate overuse and variability of procedures that only clinicians can order or to bend the escalating healthcare cost curve? What is the role of SDM to mitigate underuse of effective procedures for which there are no financial incentives or advertisements? Without financial levers or consequences, there is no evidence to suggest that patients, even if given the choice, would routinely opt for a less expensive or invasive treatment strategy. It may not be reasonable to expect SDM to be able to improve evidence-based care, mitigate overuse, and decrease cost when other initiatives such as diagnostic-related group, pay for performance, and public reporting of performance measures have had modest effects on outcomes and cost of care. Future research might further establish that the fundamental justifications for SDM reside within ethical patient-centered care presenting a moral dilemma to cost-conscious managers and policymakers.

In our experience with trials to study the efficacy of decision aids for SDM, we have found that most clinicians think they are already doing SDM, and most patients cannot...
tell that the level of their participation in usual care is inadequate. Clinicians and patients do not know or expect a better approach for decision making. This satisfaction with the status quo complicates evaluation, particularly in observational studies but also in randomized trials. Also this complicates implementation because there is no patient pull or clinician desire to change the current process for decision making. In our experience, a simple demonstration of SDM to clinicians and patients sometimes leads to challenging questions about the way we do things routinely and may represent a catalyst for interest in SDM in practice.

Future research needs to illuminate the barriers and best practices for implementing SDM in clinical practice, including but not limited to the following: patients capacity (in terms of literacy, numeracy, education, resilience, and energy) and interest in participation in decision making; clinicians capacity (in terms of duration, agenda, tools, and environment); training, and competence to engage patients in decision making; capability of current systems and policies optimized and incentivized to promote SDM; and the need to pivot our current culture and expectations for SDM.

SDM has the potential to transform health care and place the patient at the center of medical decisions. No one-size-fits-all, or even fits-most, approach is apparent for how to do SDM in clinical practice. In this series of articles in Circulation: Cardiovascular Quality and Outcomes, our goal is to summarize the latest science about SDM and provide a toolkit for investigators interested in performing research in SDM and for clinicians and clinical policymakers interested in implementing SDM in practice. We are convinced that SDM would advance patient-centered care and reframe medical decision making to a state where all fateful decisions reflect not only the best available research evidence but also the informed preferences and the context of the patient.

Disclosures

None.

References


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