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ANALYSIS Potential Unintended Consequences Of Recent Shared Decision Making Policy Initiatives

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Abstract

Shared decision making (SDM)—when clinicians and patients make medical decisions together—is moving swiftly from an ethical ideal toward widespread clinical implementation affecting millions of patients through recent policy initiatives. We argue that policy initiatives to promote SDM implementation in clinical practice carry the risk of several unintended negative consequences if limitations in defining and measuring SDM are not addressed. We urge policy makers to include prespecified definitions of desired outcomes, offer guidance on the tools used to measure SDM in the multitude of contexts in which it occurs, evaluate the impact of SDM policy initiatives over time, review that impact at regular intervals, and revise SDM measurement tools as needed.

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The collaborative process of clinicians and patients making medical decisions together, termed shared decision making (SDM), involves clinicians and patients together evaluating the evidence of intervention risks and benefits; considering patients' preferences, goals, values, and concerns; and arriving at a decision.[1]

SDM was introduced by the 1982 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[2] Since that time, a considerable amount of literature has been devoted to SDM. The process follows broader cultural trends in patient empowerment and consumer choice and renegotiates the paternalistic role that the medical profession historically wielded in society. More recently, investigators have sought to quantify SDM in care delivery through measures rated by patients, clinicians, or observers. A recent review identified over forty available instruments.[3] In addition, interventions to promote SDM, such as patient decision aids, have been developed and tested —particularly for elective surgery, cancer screening, and other "preference-sensitive" decisions.[4]

In recent years SDM has begun moving swiftly beyond research and theory toward policy and widespread clinical implementation. For example, the Centers for Medicare and Medicaid Services now mandates SDM as a condition of reimbursement for low-dose computed tomography lung cancer screening, left atrial appendage closure for atrial fibrillation, and selected cases of implantable cardioverter-defibrillator placement. This shift seems long overdue for such an intuitive concept. Indeed, SDM-promoting interventions have been shown to improve patients' knowledge of options, outcomes, and risks and to provide clarity about what matters most to patients.[5,6]

However, as a group of ethicists, clinicians, and researchers who study SDM, we worry that this shift away from theory and toward common application is premature in some ways. In particular, current policy initiatives promoting SDM implementation in clinical practice may exacerbate lingering definitional and measurement limitations that remain unaddressed. Although there are several instruments available to measure facets of SDM, they have largely been developed for research purposes, not clinical care or reimbursement. Furthermore, a recent systematic review found that many of the published SDM measures did not meet benchmarks for methodological quality,[3] which could bias research results and misinform care delivery. Most concerning, however, is the fact that existing instruments may, in some ways, foster ethically problematic implementation and assessment in routine clinical care.

SDM implementation is a laudable policy goal. Yet it must take seriously the potential for unintended consequences, such as those that have occurred with other well-intentioned policies. For example, there is evidence that pay-for-performance reimbursement methods have increased health disparities[7] and that policies to increase transparency in drug pricing have precipitated misunderstanding about actual out-ofpocket expenses and led to undertreatment.[8] In this article we outline concerns about potential unintended consequences and offer recommendations to improve SDM implementation in policy and practice.

Potential Unintended Consequences

INCENTIVIZING SHARED DECISION MAKING AS AN ARTIFICIALLY DISCRETE EVENT

How do those assessing SDM accurately measure the process of SDM over time? SDM can seem straightforward in situations that involve a well-characterized one-time decision, such as whether to have elective knee replacement, colon cancer screening, or selected types of breast cancer treatment (for example, when considering mastectomy versus lumpectomy with radiation therapy). However, many health care decisions evolve over time. In contrast to a single yes-or-no decision, multiple complex deliberations occur over the course of illness for patients with chronic illnesses such as congestive heart failure and advanced kidney disease or patients with recurrent advanced cancer. Most theorists of SDM agree that decision making may unfold over time, in multiple interactions, and with different clinicians.[1]

Nevertheless, many current SDM assessment tools presuppose that definitive decisions occur in a single encounter. This likely reflects SDM research that has preferentially focused on socalled single-event decisions, such as a decision to have a bare metal stent versus a drug-eluting stent for coronary artery disease.[9] Reliance on tools that assume that SDM occurs in a single event may encourage clinicians to pick an event in which to measure SDM, if only to satisfy insurance requirements. Such a focus could also penalize clinicians who comanage chronic disease with patients for whom there is not a single SDM event to measure. It could also encourage clinicians to pack too much SDM into single encounters, disrupting a more natural and patient-centered longitudinal evolution of important decisions.

INCENTIVIZING HYPERINDIVIDUALISTIC DECISION MAKING

How does SDM measurement accommodate the important role of family members and others in the process? While there is nothing inherent in the SDM model that precludes family involvement, most SDM assessment instruments assume a sole individual making decisions for herself along with a health care professional. These measures typically do not account for family values, preferences, or interests or for patients' preferences for family involvement. While the patient is appropriately the main focus of SDM (and we need to do a better job of meeting the primary goal of informed and involved patients), in reality, family members and others often do play a significant and legitimate role.[10] And though there are autonomy-related risks associated with overemphasizing the role of family preferences and values, many patients want their family members to be involved and to know how different options will affect them.[10,11] The use of SDM instruments that focus solely on the individual to assess SDM may unintentionally result in the crowding out or exclusion of family members, rendering decision making as occurring only within the patient-provider dyad. Communally oriented minority cultural groups may be particularly vulnerable.

Few SDM measurement instruments attempt to consider SDM within a broader social context, and when they do, the treatment is cursory. For example, Clarence Braddock and colleagues' informed decision-making coding schema asks whether the physician addressed the patient's desire for the input of "trusted others."[12] However, the framework requires observing, recording, analyzing, and coding each individual encounter—a method rarely used by busy clinicians and unlikely to be routinely implemented in practice to measure SDM. The Decisional Conflict Scale, a popular patient report survey used to measure SDM, includes only one question about whether the patient "had enough support from others to make the choice."[13] This single item is unlikely to sufficiently capture the depth of family involvement and social support discussed above. Thus, overemphasizing the individual when measuring SDM will bias what policy makers and practices pay attention to in implementation.

The same is true for pediatric populations and adults with limited capacity for decision making (for example, patients with dementia). Although these populations are not currently the focus of SDM policy interventions, they may be in the foreseeable future as policy initiatives expand. The aforementioned systematic review identified only one instrument for use in pediatrics, and it was restricted to pediatric palliative care.[3,14] No instrument was found to specifically measure SDM with surrogate decision makers, although one instrument (in Hebrew) was found to measure SDM with patients who had severe mental illness, where presumably a surrogate decision maker was involved.[15] Without validated approaches to measure SDM in these contexts, implementation and assessment may be subject to significant variation, which makes interpretation of the clinical value a challenge.

INCENTIVIZING OVEREMPHASIS ON INFORMATION EXCHANGE

What does it mean to truly share a decision? Many existing SDM measurement instruments, and the tools developed to support SDM, predominantly focus on information disclosure and exchange.While providing information regarding risks, benefits, and alternatives and soliciting information about patient values is necessary (and certainly integral to informed consent), it is not sufficient. These elements fail to embrace the meaningful shift in the doctor-patient relationship that is embodied by SDM—a shift in which patients are acknowledged as true partners and experts in their own lived experience and context of care. In addition to disclosure, the process of sharing a decision involves clinicians and patients deliberating together, sharing power, and developing a relational bond. Currently, most SDM instruments do not attend to these relational factors, as very few assess negotiation, shared agenda setting, power dynamics, active listening, or engagement. These aspects, which go beyond asking patients whether their goals and values were discussed or information was disclosed, are core aspects of SDM.

An illustrative isolated example of admirable attendance to relational factors is the nineitem Shared Decision Making Questionnaire (SDM-Q-9). It asks whether the patient felt as if "we selected the option together."[16] Yet this is the only relevant item in the SDM-Q-9—and to our knowledge, the SDM-Q-9 is one of the few instruments that attempts to address relational factors. The predominant focus on information exchange in many of the SDM measurement instruments may encourage providers to focus excessively on information exchange and lead to the development of SDM support tools (such as videos, written tools, and interview guides) that do the same, crowding out the relational core of SDM. It is also worth noting that assessment of information exchange and transfer is different from assessment of actual knowledge, which is also important for high-quality decisions and should be assessed separately (for example, see the knowledge measure for hip and knee replacement surgery endorsed by the National Quality Forum).[17,18]

IMPLYING THAT PATIENTS CANNOT DELEGATE DECISIONS

Patients may wish to defer decision making to their providers or not receive information about certain aspects of the decision. In this scenario, can the success of SDM be measured —and if so, how? Many scholars might argue that delegating a decision would not count as SDM. Indeed, many instruments seem to reflect this view. Some SDM instruments, such as the SDM-Q-9, include a question asking whether the patient was asked how she wanted to be involved. Yet the instrument goes on to assume that patients want (or should want) to be involved in all aspects of the process (including making the final decision), since the remaining questions are relevant only in that context. Thus, patients who do not want to be as involved would by necessity score low on SDM.

This assumption does not respect the agency of the patient, however. If a patient is asked how she wants to make decisions and chooses to defer to the physician, there is a sense in which the process is very much shared (the patient had input), even though the final decision has been delegated to another. Moreover, deferral is not binary—a patient may want to be involved in some aspects of the SDM process (that is, to be informed, involved, and heard) but might not want to have “final say authority.”[19] This feature of decision making could be accounted for in assessments of role preferences and concordance, such as through the use of the Control Preferences Scale. However, these measurement scales would need to be integrated into other formal assessments of SDM.[20]

Even if one takes the view that deferral of decision making and SDM are incompatible, it should be acknowleged that good decision making does not, by necessity, have to be shared in every circumstance. Deferring to a clinician can be ethically defensible if that is the patient’s preference. If ethically defensible decision making— and indeed, patient-centered decision making— extends beyond SDM, we need mechanisms to reflect a clinician’s effort to engage in the process of SDM, while recognizing that respecting a patient’s deferral of decisions to the clinician can still represent high-quality care.

Nonetheless, it is important to be aware that people tend to express desires that reflect prior experiences. Thus, stated preferences for decision making (for example, playing a passive role) may be due, in part, to limited historical engagement by providers in the SDM process. Marginalized populations with limited power associated with their social identities (for example, members of racial/ethnic minority groups; lesbian, gay, bisexual, and transgender people; and people with disabilities) have disproportionately been less engaged in SDM than have other groups with more social power.[21–23] Thus, requests for passive roles among such patients should be interpreted with caution. We should explore the underlying reasons more fully before proceeding with paternalistic provider roles for marginalized patients.

ASSUMING PHYSICIAN NEUTRALITY

Should providers remain “neutral” in SDM about the options available to patients? While conceptual models of SDM have often recognized the presence of physicians’ values, preferences, and recommendations in the decision-making process, existing tools that measure SDM do not assess these factors. This absence may contribute to an implicit assumption that provider neutrality is a goal of SDM. Indeed, anecdotally, many of us have had colleagues who have expressed this view. This may especially be the case with providers in younger generations who are more uncomfortable making recommendations or being directive in the context of preference-sensitive decisions.[24,25] However, complete neutrality might not be possible and is often not desirable in many clinical decisions.[26–28] Indeed, a physician's desire to maintain decision neutrality can be undermined by subtle factors. Recent research in behavioral economics has demonstrated that simple conversational elements such as how options are introduced—for example, whether information is presented in a negative (odds of mortality) or positive (odds of survival) way—can influence and shape patient choice.[29] It is important to recognize that physician recommendations, choice architecture, and other forms of influence can be an ethically acceptable part of SDM. Part of the physician's fiduciary obligation is to help patients make decisions that best protect and promote their interests, after taking time to understand their values and goals.

IGNORING SOCIAL AND PUBLIC HEALTH INTERESTS

How do should SDM processes and measurements account for the role of public health? Some shared decisions involve stakeholders outside of the clinical relationship, as some clinical decisions affect the larger community. This is particularly true in the case of infectious diseases—their prevention (that is, vaccinations), screening or testing (for example, for sexually transmitted diseases), and treatment (such as the use of antibiotics and attempts to mitigate the spread of antibiotic-resistant strains of bacteria). While it is clear that some clinical decisions have an impact on public health and society, it is unclear if, when, and how SDM should be involved in such decisions. None of the current SDM instruments consider risks and benefits of the decision to people beyond the individual patient, yet from an ethical perspective, these should at least be important points of consideration in an SDM process.

Solutions

One might think that the answer to the above concerns is that the measurement of shared decision making simply needs to be improved in ways that take these issues into account. For example, if instrument developers simply ask more nuanced questions about surrogate involvement, this concern can be addressed. Though more nuanced and comprehensive measurement is necessary, it is insufficient. It is unlikely that an instrument can be created that can accommodate all necessary considerations in SDM.

Instead, we believe that there needs to be an emphasis on revising policy initiatives that encourage effective SDM. Foremost, translation of SDM into policy must avoid the oversimplification of SDM. To achieve this, the tools used to define and measure SDM need to be ethically grounded and meaningful in the multitude of contexts within which they are applied. Policy makers could meet this objective by recommending the use or prioritization of specific instruments (new or existing) that are methodologically strong and avoid some of the ethical pitfalls we have highlighted here. Alternatively, policy makers could develop checklists of desirable qualities and potential pitfalls that implementers should consider when selecting the approach or instrument they will use to assess SDM success in their setting. Relatedly, policy makers should include prespecified definitions of desired outcomes. Finally, policies should be pilottested before they are enacted—or, at least, their impact should be evaluated over time and plans should be made to review them and their impact at regular intervals. Recent controversies regarding the impact of policies to reduce unnecessary hospital readmissions[30] or publicly report procedural outcomes in cardiology[31] illustrate the importance of pilot-testing with periodic reevaluation of policy impact.[32]

The use of SDM in chronic disease management and public health represents a significant departure from the contexts in which most existing SDM measures were developed. Thus, policy makers will need to take particular care to ensure that new tools are developed and tested for these contexts (or make recommendations regarding existing instruments) before issuing policies that mandate or incentivize SDM in these contexts. This will be difficult and could require reconceptualization. For example, SDM in chronic illness management will need to be more longitudinal, relational, and qualitative than SDM in discrete events, which is challenging from a measurement perspective. The use of SDM in decisions that have significant impacts on the public (in terms of health or resources) is also challenging. Providers need normative and evaluative models to guide them in discussing a medical intervention's benefits and burdens for the individual versus the public in a way that is not overwhelming to the patient, still feels "shared," and accounts for the fact that it is difficult for most people to consider the good of the community beyond themselves.

A final recommendation for policy makers is to not lose sight of decision quality, of which SDM is one part.[1] Other aspects of decision quality include knowledge, realistic expectations, and alignment of patients' actual treatment choices with their expressed preferences and goals.[33] A focus on decision quality more broadly could mitigate some of the potential negative consequences discussed in this article (for example, resulting in less focus on an artificially discrete event or more openness to decision delegation). On the other hand, measurement issues plague decision quality as well, and too narrow a focus on decision quality (of which knowledge is often a primary outcome) could crowd out the benefits of SDM: relationship building, patient engagement, and patient empowerment.[34] We do, however, believe that there is merit in focusing on both decision quality and SDM in policy.

Conclusion

Shared decision making holds considerable promise for having a positive impact on modern health care. To realize that potential, the barriers outlined here must be overcome so that those in charge of implementing and assessing SDM can know what they are measuring and ensure that these measurements correspond to meaningful encounters in the lives of patients, families, and practicing clinicians. As policy initiatives for SDM move forward, we must ensure that the tools we are using to define and measure SDM are valid and meaningful in the multitude of contexts within which they are applied. Otherwise, we risk measuring the wrong thing and aiming for the wrong goal.

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