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Shared decision-making and comparative effectiveness research for patients with chronic conditions: an urgent synergy for better health

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Abstract

Chronic conditions are the most important cause of morbidity, mortality and health expense in the USA. Comparative effectiveness research (CER) seeks to provide evidence supporting the relative value of alternative courses of action. This research often concludes with estimates of the likelihood of desirable and undesirable outcomes associated with each option. Patients with chronic conditions should engage with their clinicians in deciding which of these options best fits their goals and context. In practicing shared decision-making (SDM), clinicians and patients should make use of CER to inform their deliberations. In these ways, SDM and CER are interrelated. SDM translates CER into patient-centered practice, while CER provides the backbone evidence about options and outcomes in SDM interventions. In this review, we explore the potential for a SDM–CER synergy in improving healthcare for patients with chronic conditions.

Keywords

chronic condition; comparative effectiveness research; shared decision-making

Critical definitions

Shared decision-making (SDM) describes the work that patients and clinicians do together to consider the relative merits of available management options and decide on a plan that fits the patient goals, preferences and context.

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Comparative effectiveness research (CER) seeks to determine the benefits and harms of alternative options for prevention, diagnosis and treatment to enable decision-makers (e.g., patients and clinicians) to make informed clinical and policy decisions [1].

Legaré and Witteman recently proposed a concise definition of SDM that illustrates the alignment in objectives between SDM and CER well [2]. This definition characterizes SDM as an ‘interpersonal and interdependent’ process composed of three essential elements: recognition of the need for a decision; understanding of the best evidence for risks and benefits; and consideration of the provider’s guidance and the patient’s values and preferences.

SDM and CER relate to each other in two ways: first, CER offers estimates of the benefits and harms associated with each option. Clinicians and patients should make use of this CER evidence to inform their deliberations to enable patient-centered decision-making. Thus, SDM is a way to translate CER into patient-centered practice. SDM requires patients and clinicians to consider the best evidence about the relative effectiveness of alternative courses of action. SDM must therefore judiciously apply the results of CER for it to avoid being fraudulent. Second, interventions that promote SDM can be delivered using various approaches (e.g. within the clinical encounter or with a health coach outside the clinical encounter; electronic or paper-based, among others), but evidence-based best practices are sparse. Research comparing the effectiveness of different SDM interventions may improve their implementation in routine care.

In this paper, we will explore these SDM–CER relationships in the setting of healthcare for patients with chronic conditions. Nontransmissible chronic conditions are the most important causes of morbidity and expense in the USA [3,101]. Care for these patients offers an urgent and exciting opportunity for both SDM and CER. We will provide an overview of the origins of SDM, review the CER of SDM as an intervention in this context and consider future challenges and opportunities for SDM and CER.

Brief history of SDM

The term ‘shared decision-making’ in healthcare might have appeared in the medical literature over 30 years ago [4], but its underlying model of mutual participation was first described in 1956 [5]. The mutual participation model represented a departure from medical practice solely as a clinician-driven activity and introduced it as a give-and-take relationship, based on equality and respect. Even from its earliest stages, this model was felt to be particularly useful in the management of chronic conditions [5]. This recognition that behavioral, psychosocial and lifestyle interventions, in the hands of patients, could affect health beyond the effect of biomedical interventions, furthered the interest in engaging patients in healthcare [6]. It was in this context of changing ethical and clinical thought that SDM began to develop an identity: in 1982, a Presidential Commission Report concluded that “shared decision-making is the appropriate ideal for patient–professional relationships” [4].

At first, the practice of this ‘appropriate ideal’ manifested primitively as informed consent and patient education [7]. It was not until the late 1990s that Charles *et al.* provided a formal framework for the application of SDM in clinical practice [8]. They highlighted the need for bidirectional information exchange, participation of both parties in deliberation and agreement about the resulting plan. This framework, developed in the context of one-time decisions, is the most commonly cited framework for SDM interventions [9].

Since then, the understanding and application of SDM has grown into an attitude or overarching approach to care delivery. In this way, SDM represents a meaningful approach

to improve the quality of care by promoting patient-centered care [10]. In moving from specific actions at the point of care to an attitude or stance, SDM has lost some specificity while enhancing its reach. SDM is now considered a keystone of not only individual patient–clinician consultations, but also of the practices and culture of health systems, and even national health policy [9,11–13].

The Salzburg Statement on Shared Decision-making [14], the product of international collaboration in formulating SDM’s core goals, was released in early 2011 and, although it called on patients and clinicians to “work together to be coproducers of health” through the appropriate provision of two-way communication, it did not establish a firm definition for what SDM ought to be and was silent with respect to patients with chronic conditions.

SDM in chronic conditions

Although SDM, as a concept, has been particularly connected to the clinical context of chronic conditions since its inception, the exact reasons for this logical fit have only been described in recent years. Chronic conditions are characterized by cumulative consequences of management decisions, and are thus optimal opportunities to consider long-term risks and benefits in the context of patient values and preferences. Chronic conditions, as described in the US Department of Health and Human Services strategic framework for multiple chronic conditions, last more than 1 year and require ongoing management and/or limit activities of daily living (e.g., diabetes, hypertension and chronic back pain) [15]. These sorts of clinical contexts are different in important ways from those that involve acute conditions (e.g., acute pancreatitis and acute-myocardial infarction) and one-time, irreversible management options (e.g., screening tests and total knee arthroplasty).

In 2006, Montori, Charles and Gafni modified the Charles *et al.* framework [8] to make it more applicable to the care of patients with chronic conditions [16]. This modification stressed the need for an ongoing partnership between clinicians and patients that is essential in the context of chronic conditions, but may not be a necessary or possible requisite in the acute setting. The other components of the framework remained nominally similar with the recognition that in chronic care decision-making there is the opportunity to revise decisions. This longitudinal deliberation cycle is illustrated in Figure 1 and requires that SDM is modeled as a partnership between the patient and the clinician [16]. The opportunity for these revisions results from the long-term effects of disease and treatment such that only small losses may accrue when the chosen paths turn out to be undesirable (e.g., when a patient develops an uncommon side effect) and a different approach is then chosen without loss in the patient–clinician partnership.

There are 52 randomized trials of SDM interventions tested in the context of 16 chronic conditions and reported in 57 publications [17–79]. Most of these trials refer to the implementation of patient decision aids (tools that communicate the evidence about the relative merits of the available options in order to facilitate patient participation in decision-making) and not necessarily measure whether SDM took place. These trials also evaluated patient education, audiotaping of consultations, patient training or coaching programs, and physician training programs. In most cases, comparators were either usual care or the provision of generic patient education materials with no study comparing between SDM interventions. Furthermore, the narrow range of populations (overselected by strict eligibility criteria or by the rigor of trial participation) and settings (often single academic centers) reduces the confident application of this evidence outside of those contexts. All of these limitations preclude the generation of firm conclusions about the effectiveness of SDM interventions and, as such, may be holding back the acceptance and implementation of SDM

interventions in the care of people with chronic conditions. In other words, CER about SDM delivery models is both lacking and needed.

The task of conducting CER about SDM requires some additional work. First, considerable variation exists in the processes of operationalization and implementation of SDM interventions. This is in part due to differences in the developers' perspective of what constitutes SDM. As Durand *et al.* have found, this variation, however, remains hidden as most decision aid developers fail to disclose the definition or framework or theoretical rationale for their approach [80]. The resulting tools differ in their structure and function, but also in the environment in which they are assumed to work. Some tools are designed as patient education materials for use prior to the consultation to promote informed patient choice. Other tools are designed to promote an informed interaction between the patient and the clinician during the encounter [81]. The consequence of this is that it becomes difficult to assign value to interventions when it is unclear where the credit for effectiveness should lie. As a result, those appraising the SDM CER evidence must operate under the assumption that the mode or method of SDM makes no difference on outcomes. This is probably an invalid assumption.

Up until recently, there has been no standardized approach for the development of SDM tools. However, in 2006, the International Patient Decision Aids Standardization (IPDAS) Collaboration created a checklist to evaluate the quality of decision aids [82] and further guidance was released in 2012 [102]. It is difficult to know to what these standards apply, given the diversity of tools and approaches that might fall in the category of patient decision aids. If one were to conceptualize decision aids as in an early stage of development, standards might represent a form of premature closure on the features that are needed and sufficient for their success in producing SDM. The impact of these standards on the quality of decision aids and on the likelihood of SDM remains unclear. In this discussion, we run the risk of conflating the use of tools or interventions to promote SDM with the attitude, approach or actions of SDM in practice, a relationship that is at best incomplete.

A second challenge to the development of comparative effectiveness about SDM relates to the lack of a standardized measurement set for SDM. Many authors have attempted to develop measures to gauge the quality of SDM [83,84]. These measures have proven largely to be discordant [85,86]. This lack of concordance reflects variations in the conceptualization of SDM used to develop the measures and variations in the particular construct that is being measured (e.g., clinician performance, patient experience, deliberation process and decision as outcome) [87]. Limitations in SDM measurement undermine our confidence in the estimates of SDM efficacy. While there are a few measures that are commonly used (e.g., the Control Preferences scale [88] and the Decisional Conflict scale [89]), their common usage does not imply that these measures have both adequate measurement properties (e.g., all relevant forms of validity and responsiveness to change) and congruence with the conceptualization of SDM used to develop the intervention being tested. The same lack of measurement clarity affects outcomes not directly related to SDM but felt to be consequential to its presence or absence. These include medication adherence, patient satisfaction, decisional conflict, patient knowledge, clinical encounter time and a variety of condition-specific outcomes.

SDM–CER synergy in chronic conditions

In the introduction to this paper, we outlined the important relationships that need to be fostered and promoted to help advance the agendas of both SDM and CER and encourage meaningful improvements for diverse patient populations. Funding agencies and institutes such as the Institute of Medicine, NIH, Agency for Healthcare Research and Quality,

Patient-Centered Outcomes Research Institute, Centers for Medicare and Medicaid Services, and others are committed to the ideals of both fields and seem primed to support work that can fully embrace their potential. Specifically, CER should provide the evidence backbone for SDM; CER should be applied to compare alternative implementations of SDM in practice; and SDM should be used to translate CER into practice.

Several recent conferences [90] and grants (e.g., Agency for Healthcare Research and Quality's Innovative Adaptation and Dissemination of CER), have highlighted the potential synergy between SDM and CER. Most recently, in June of 2013, SDM stakeholders from around the globe gathered in Lima (Peru) for the 7th International Shared Decision-Making Conference [103]. A symposium at the conference was devoted to the role SDM can play in CER translation and promising work was demonstrated in the context of a variety of chronic conditions:

- An ongoing study (TRICEP, started in 2011) is assessing the primary care use of a decision aid (Diabetes Medication Choice Issue Cards) [62] to translate CER about diabetes medications for patients with Type 2 diabetes. Results from a survey of primary care physicians of sites involved with this study [91] demonstrated that most primary care physicians were not familiar with CER, but were much more familiar with SDM and felt it might be a good way to translate evidence;
- An SDM–CER partnership seemed to demonstrate particular promise in the context of diverse or vulnerable populations where it may serve as a way to reduce disparity, normalize practice variations and improve outcomes. Work from a study in the Carolinas Healthcare system showed significant reductions in emergency room visits, hospitalizations and oral steroid use in a relatively vulnerable patient population that received an SDM toolkit [92];
- In the context of rheumatoid arthritis, a low literacy decision aid adapted from an Agency for Healthcare Research and Quality CER-based tool and translated into three languages at the University of California (CA, USA) was feasibly used in outpatient clinics leading to improvements in knowledge and decisional conflict [93];
- Finally, in a practical randomized trial, another set of issue cards, this time focused on antidepressants, based on CER showed improvement in decisional conflict in rural and urban primary care sites [94]. These examples show how SDM might correct practice patterns, health disparities and CER translation failures by subjecting treatment and management decisions to the deliberative conversations between informed patients and clinicians.

These practical examples illustrate how CER, even when the research warrants low confidence in the results, can provide estimates of the likelihood of relevant outcomes across alternatives to populate SDM interventions and support the provider's guidance. Most of the evidence supporting decision-making and included in decision aids, is comprised of indirect comparisons between interventions, as most fields lack trials testing direct comparisons between active interventions, with most assessing the efficacy of interventions against placebo [95]. Improvements in CER might, therefore, improve the evidence base supporting clinical decision-making, an urgency acknowledged in the founding mission of Patient-Centered Outcomes Research Institute.

The existing literature suggests that there is great policy interest in SDM for chronic conditions [12,13]. Indeed, 110 randomized trials included in the latest update of the Cochrane Collaboration Systematic Review of decision aids (a type of SDM intervention)

for screening and treatment [96] clearly support the efficacy of these tools. However, questions remain about how SDM interventions are implemented, deployed and routinized in clinics, and about the comparative effectiveness of these SDM implementations. These questions require careful study.

CER results could be translated into practice through two general strategies: practice- or population-based policies, or patient-centered approaches. Practice guidelines, formulary design and quality-of-care frameworks for accountability, public reporting and reward are examples of the former. The practice of SDM, with its requirement of considering information about the available options and outcomes, offers a patient-centered approach to the translation of CER. The relative effectiveness or complementarity of these approaches deserves full exploration [97].

Conclusion

SDM should be applied to the translation of CER about management options into practice in a patient-centered manner. CER results should provide the evidence backbone of SDM interventions. CER methods should be applied to evaluate SDM implementations. Without CER about alternative management strategies, using SDM to find the best option would lack validity. Without SDM, CER translation might not improve patient-centered care and outcomes. Without CER about SDM, SDM interventions might never get implemented into practice. This synergy, when embraced, can advance the agendas of both fields and improve the health of patients – particularly those with chronic conditions – in a way that is evidence-based, patient-centered and practically relevant.

Future perspective

We have identified the following unanswered (or partially unanswered) questions as particularly relevant to advancing the field of SDM research:

- What are the characteristics of interventions that must be present to define an intervention as promoting SDM?
- What are the characteristics of measurement approaches that make them required components for the evaluation of interventions to promote SDM and to compare the effectiveness of SDM interventions?
- What are the characteristics of CER, for example, selection of patients, interventions, comparisons, outcomes and designs, that make it amenable to patient-centered translation via SDM?
- In what ways can work to advance CER and SDM be synergized to improve health quality and patient care?
- Is SDM superior or complementary to policy approaches to the translation of CER into practice?

As these questions receive attention and effort is made to answer them, it ought to be our minimal goal to ensure that CER results find their way, when timely, into the clinical decision-making process. SDM interventions may provide a useful conduit for this, and we should identify optimal implementation strategies for them, since lack of routine use of SDM tools may annul their value. Finally, high quality CER should provide the evidence base of SDM tools [102]. Coming full circle, the synergy of CER and SDM will realize the value of both the comparative effectiveness enterprise and of the collaborative engagement of clinicians and patients with chronic conditions working together to make clinical decisions.

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Executive summary

Background

- Shared decision-making (SDM) is the work patients and clinicians do together to consider alternative management options and their desirable and undesirable characteristics as informed by the best available evidence from comparative effectiveness research (CER). SDM translates CER in a patient-centered fashion. CER provides the evidence backbone for SDM interventions. CER can be applied to compare the effectiveness of different ways of implementing SDM interventions.
- The use of SDM interventions in patients with chronic conditions is not well documented in randomized trials of SDM interventions. The extant literature, while inconsistent, suggests that SDM interventions, particularly decision aids, are efficacious. Sparse data about effectiveness may be contributing to the limited use of SDM in the care of patients with chronic conditions.

SDM–CER synergy in chronic conditions

- We have identified a conceptual and practical synergy between SDM and CER. Improvements in CER (e.g., direct comparisons) will improve the content of SDM. Improvements in the CER of SDM (e.g., conceptual and methodological consistency and larger studies) will improve the evidence base about the relative effectiveness of SDM implementations. Improvements in SDM will, among other effects, help translate CER to improve patient outcomes.

Conclusion

- A synergy between SDM and CER may be able to advance the agendas of both fields and improve the health of patients – particularly those with chronic conditions – in a way that is evidence-based, patient-centered and practically relevant.

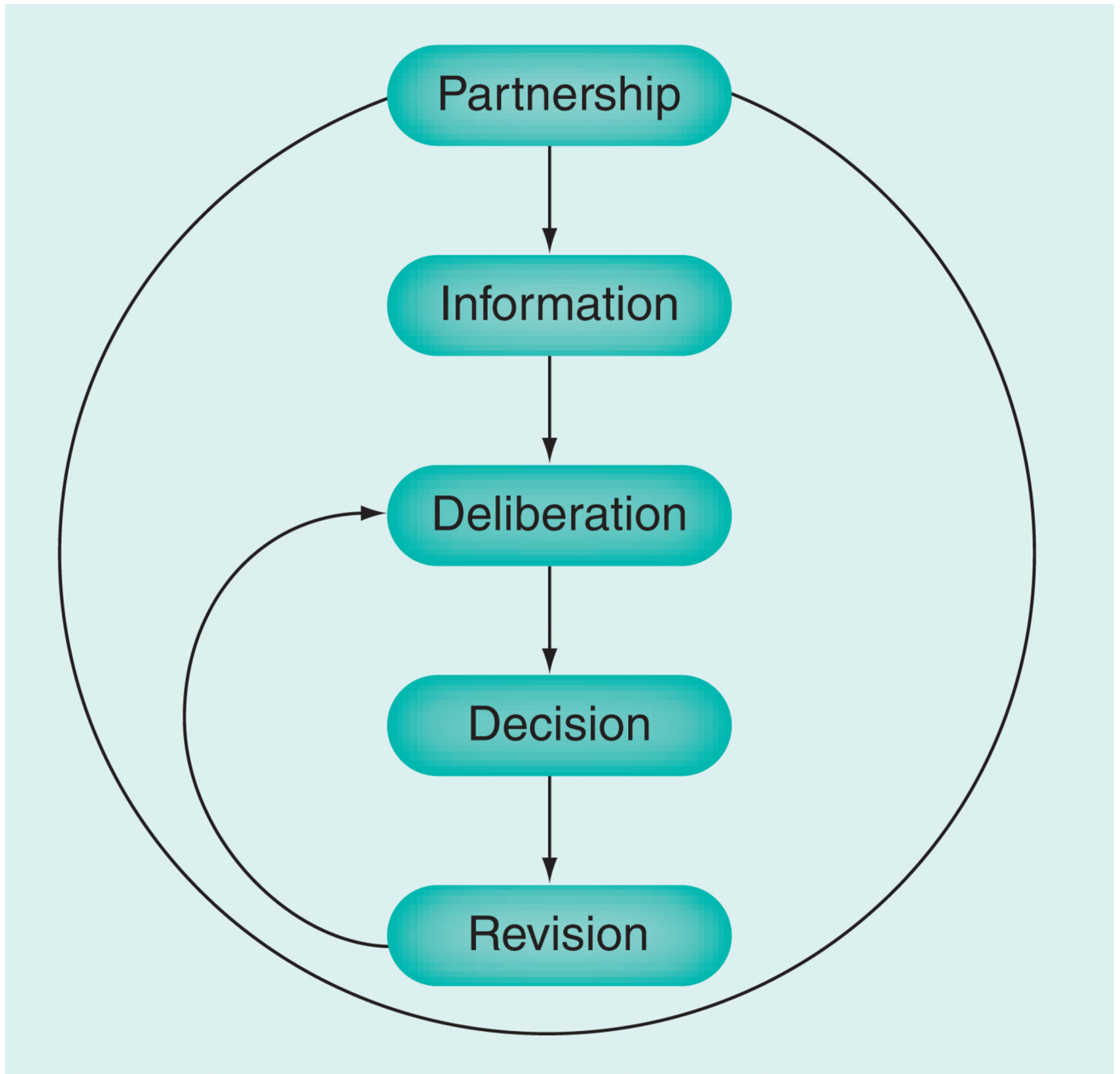


Figure 1.
Model of shared decision-making in chronic conditions.