

IMPLEMENTING SHARED TREATMENT DECISION MAKING AND TREATMENT DECISION AIDS: A CAUTIONARY TALE

IMPLEMENTACIÓN DE LA TOMA DE DECISIONES COMPARTIDAS Y AYUDAS A LA TOMA DE DECISIÓN EN EL TRATAMIENTO: UNA ADVERTENCIA

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Resumen

El interés en la toma de decisión médica compartida y en las ayudas a la toma de decisión se desarrollaron en los años ochenta y noventa con un foco inicial en pacientes con cáncer, y en particular, en mujeres con cáncer de mama. Este interés con el tiempo ha experimentado un cambio en énfasis desde la curiosidad acerca del significado de estos conceptos y su potencial para mejorar la participación del paciente en la toma de decisión a una promoción a gran escala, intentos de expansión, implementación en una variedad de situaciones clínicas, medición de resultados múltiples en niveles clínicos y de política pública y el desarrollo de criterios estandarizados para evaluar las ayudas a la toma de decisión. En este artículo planteamos la cuestión: ¿estamos moviéndonos demasiado rápido en la promoción de la decisión médica compartida y de la ayuda a la toma de decisión antes de resolver los importantes desafíos que todavía existen acerca del significado y los méritos de estas iniciativas?

Discutimos cuatro desafíos: i) ambigüedad e inconsistencia en la definición de la decisión médica compartida; ii) variaciones en las preferencias de médicos y pacientes sobre la decisión médica compartida; iii) el incremento en el número y rango de metas definidas para lograr con la toma de decisión compartida y/o la ayuda a la decisión; iv) la carencia de apoyo teórico y empírico bien documentado para los

Abstract

Clinical and research interest in shared treatment decision making (STDM) and decision aids (DA) evolved in the 1980's and 1990's with an initial focus on patients with cancer, and particularly, women with breast cancer. This interest has undergone a shift in emphasis over time from curiosity about the meaning of these concepts and their potential to improve patient participation in treatment decision making to wide scale endorsement, attempts to expand implementation in a variety of clinical settings, measurement of multiple outcomes at the clinical and public policy level, and the development of standardized criteria for evaluating DA. In this chapter we raise the question: are we moving too fast to promote implementation of STDM and DA before resolving important challenges that still exist about the meaning and merits of these initiatives?

We discuss four such challenges: i) ambiguity and inconsistency in the definition of STDM, ii) variations in patient and physician preferences for STDM, iii) the increase in the number and range of goals defined for STDM and /or DA to achieve, and iv) the lack of well documented theoretical and empirical support for criteria to be used in evaluating DA quality, and potentially for purposes of DA certification. These findings suggest the need for caution, for more thoughtful analysis, and

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critérios usados en la evaluación de la calidad de las ayudas a la decisión, y potencialmente para los propósitos de la certificación de la ayuda a la decisión. Estos hallazgos sugieren la necesidad de precaución, un análisis más meditado e investigación adicional en los desafíos mencionados previamente a la promoción a gran escala de la decisión compartida y las ayudas a la decisión en la práctica clínica habitual.

Palabras clave. Decisión médica compartida, ayudas a la decisión.

Background

Clinical and research interest in shared treatment decision making (STDM) and decision aids (DA) evolved in the 1980's and 1990's. The development and evaluation of decision aids in cancer initially focused on women with breast cancer, and to a lesser extent men with prostate cancer⁽¹⁾. Over the last 20 years, the number of papers and books written on STDM and DA has grown dramatically, and specific topics of research and clinical policy interest have undergone some shifts in emphasis. For example, during the 1990's STDM was advocated as a way to create more informed patients and to help involve patients in treatment decision making^(1,2). Patient involvement was seen as a means of achieving ethical principles such as patient autonomy and patient choice⁽¹⁻³⁾. Discussions of STDM were embedded within the context of the physician patient relationship⁽⁴⁻⁸⁾ and were often advocated as a way to counterbalance the more common paternalistic approach to decision making in which physicians played a dominant role⁽²⁾.

Consistent with this focus, conceptual activities undertaken during this time centred on various attempts to develop conceptual frameworks or ways of thinking about the defining characteristics of STDM as an approach to treatment decision

additional research on the challenges raised above prior to wide scale endorsement of STDM and DA in routine clinical practice.

Key words: Shared treatment decision making, decision aids.

making in the medical encounter and how this approach differed from other approaches commonly talked about and/or used; for example the paternalistic approach, the informed approach and the physician as perfect agent approach⁽⁴⁻⁸⁾. This type of conceptual work is still being undertaken and will be referred to later in this paper⁽⁹⁻¹²⁾.

Empirical research interests reflected these conceptual concerns. Researchers studied such issues as patient and physician preferences for different approaches to treatment decision making in the medical encounter⁽¹³⁻¹⁷⁾, perceived barriers and facilitators to STDM⁽¹⁸⁾ and the impact of DA on various outcomes^(1,19). DAs were developed initially to help inform patients about available treatment options and the benefits and side effects of each in order to better enable them to participate in the decision making process⁽²⁰⁾. The general goal of such tools was to improve physician patient communication primarily within the context of the medical encounter.

The use of decision aids has now spread to other clinical areas beyond cancer, in addition, conceptual and research interests in STDM have shifted in focus. Conceptually, both clinicians and researchers still struggle to define the meaning of STDM and to define steps that physicians can use in implementing this approach⁽⁹⁻¹²⁾. However, despite some

agreement, consensus on the meaning of this concept has not been achieved⁽¹⁰⁾ and other complex conceptual issues have emerged to add to this confusion. For example, STDM and DA are now often treated as synonymous and interchangeable terms in the literature, resulting in further ambiguity as to i) the meaning of each, ii) their relationship to each other and iii) expectations about the goals which each is expected to achieve. We discuss these issues later in this paper.

In terms of empirical research, there are now broader goals defined for STDM and/or DA to achieve and more outcome measures that researchers are interested in studying⁽²¹⁾. (These include, for example, a variety of psycho-social, clinical, and system level health policy goals such as a reduction in medical practice variations and health care costs. Research interest now focuses, to a large extent, on how to promote wide scale implementation of STDM and DA in a variety of clinical settings, and reflects a merging of scientific and advocacy perspectives⁽²²⁾. How to quantitatively measure patient values for different treatment options through the use of DA is another major and controversial area of research interest^(21,23). The use of decision aids as a mechanism to gain informed consent from patients is also a topic of interest.

The rapid expansion in the development of DA has raised concerns about their quality. To respond to this issue, an International Collaboration led by academic researchers have spent several years researching and developing a checklist of quality criteria to evaluate the development, content and effectiveness of DA⁽²⁴⁾. Underlying this initiative is an assumption that there is a common and uniform set of evidence based quality criteria that can and should be used to evaluate different kinds of DA, legitimizing those that are judged to meet these standards and de-legitimizing those that do not.

In summary, interest in STDM and DA has undergone a shift in focus over time from: on the one hand, curiosity as to what these concepts mean and what potential they have for facilitating patient involvement in treatment decision making, cautious endorsement of each on ethical grounds, and evaluation of a limited number of goals (or benefits) hypothesized to result from each: to, on the other hand, largely uncritical endorsement of STDM and DA, a focus on how to implement this approach on as wide a scale as possible, measurement of a variety of outcomes at the clinical and public policy level, and development and application of a standardized set of criteria for determining what counts and does not count as a high quality decision aid.

Objectives

Given the above trends, it is timely to raise the question: is the move to endorse and promote the implementation of STDM and DA being undertaken too quickly? Also, should the focus of research interest in this topic at this point be weighted towards issues of implementation (as now seems to be the case) or have we moved too fast without addressing some important and fundamental unresolved issues? We think it is time to step back and revisit some of the challenges that still exist about the meaning and merits of STDM and DA which suggest (at least to us) that a more cautionary approach is needed in thinking about widespread implementation. These challenges relate to: i) the definition and meaning of STDM; ii) variations in patient and physicians preferences for STDM, iii) the increase in the number and range of goals defined for STDM and /or DA to achieve, and iv) the lack of well documented theoretical and empirical support for criteria to evaluate DA quality, and potentially for purposes

of DA certification. We discuss these 4 challenges below.

Cautionary tales

i) What is the Meaning of STDM?

A frequently cited framework for defining STDM is that by Charles, Gafni Whelan et. al.^(6,7); who describe i) different “pure type” approaches to treatment decision making (i.e. paternalistic, shared, and informed) as well as “in-between” approaches; and ii) different stages of decision making (information exchange, deliberation and making the decision). The framework then defines the role expectations of physicians and patients in the acute care context (specifically, early stage breast cancer) by stage of decision making for the different approaches to decision making. In other words, the framework attempts to define specific behaviours for both patients and physicians that would characterize a “pure” informed versus shared versus paternalistic approach to treatment decision making. The authors recognize that these “pure” approaches are unlikely to be found in reality and that most physician /patient interactions will lie somewhere in -between these pure types. Hence, as the authors imply, those who advocate that a STDM approach be implemented as routine practice may be aiming for an approach that is, in reality, unrealistic to start with, since i) actual roles that physicians and patients play in the decision making process are dynamic and can change even within a single encounter and ii) participation of both physicians and patients in decision making may not conform to the “pure” type behavioural expectations of any single decision making approach.

Despite the finding that the Charles et. al. framework for defining the meaning of STDM^(6,7) is the most commonly cited

in the literature⁽¹⁰⁾, there is no consensus that any one framework captures the full meaning of this concept^(9,25). In so far as there is still disagreement on the meaning of STDM, attempts to measure its impact and to promote its implementation remain problematic because the concept itself is open to different interpretations. Also, variable coding schemes and measurements of STDM definitions make it difficult to compare results across studies⁽²⁵⁾.

As well, recent conceptual and empirical work have suggested that there are other dimensions to the concept of STDM which have not typically been discussed in the literature but which require further attention. For example, O’Brien, 2009⁽²⁶⁾ found in her study that several women with early stage breast cancer in Ontario, Canada reported sharing in the TDM process with their doctors, even though they reported not taking an active role in making the final treatment choice. This suggests that other factors play an important role in patient’s perceptions of involvement. Similarly, Entwistle⁽¹¹⁾ has discussed the importance of the relational aspects of the physician patient relationship to patient perceptions of involvement in the decision making process.

These finding suggest that when we talk about STDM we need to differentiate between (at least) two different ways of conceptualizing and measuring this phenomenon: STDM as i) a set of role expectations identified for patients and physicians which are thought to characterize a STDM treatment approach and which can be measured either through observation or self reports (e.g. the Charles, Gafni, Whelan et. al., framework^(6,7) or ii) a subjective feeling state experienced by patients who express *perceptions* of being involved in the treatment decision making process, even if they do not actually play an active role in making the decision. These are two different ways of thinking

about STDM and it is not clear if and how these can be integrated⁽¹¹⁾, or which of these ways of thinking (or both) is being advocated by those promoting STDM. Unless this issue is clarified, instructing physicians on how to implement a STDM approach will be problematic.

Similarly when evaluating outcomes of STDM, we need to ask whether it is more important to explore the impact of patients' observed and/or reported level of behavioral involvement in treatment decision making or to explore patient perceptions of involvement, no matter how these perceptions come about. We still do not fully understand the range of factors that trigger patients to feel involved in treatment decision making or even what involvement might mean to different patients. Thinking about different ways of conceptualizing the meaning of STDM and its implications is an important activity because the current emphasis on implementation assumes that we already know in a definitive way what STDM means and that its meaning is universal, constant and unproblematic. This is clearly not the case.

Not only are there various definitions of STDM, there are also difference in emphasis within a single conceptual framework defining the meaning of STDM in terms of the steps involved for physicians and patients in implementing this approach in different clinical practice settings. For example, using the Charles et al framework of STDM as a starting point, various clinical researchers have described modifications needed to implement this framework in different clinical areas such as diabetes⁽²⁷⁾ and general practice⁽²⁸⁾, in contrast to cancer care which was the original acute care clinical context within which this framework was developed. Hence, identifying the defining the steps of a STDM approach for purposes of implementation is not a "one size fits all" endeavor and requires sensitivity to

the specific context of different practice settings.

STDM has typically been discussed and described as an approach to TDM between doctor and patient in the clinical encounter. Increasingly, however, patients will bring a significant other with them to the encounter. This transforms the interaction from a dyad to a triad and greatly expands the interactional possibilities among the three participants. With three (or more) participants, for example, coalitions of various types can be formed between two participants who favour a particular treatment option in opposition to the views of the third participant.

To date, there have been few empirical studies or conceptual frameworks exploring this three way (or more) participation in TDM and attempting to describe what counts as STDM in this broader interactional context. Hence, the ways in which current research studies conceptualize and measure STDM in the clinical encounter may not accord with the realities of clinical practice in which the patient's significant other(s) may play a variety of roles (e.g. listening to and/or recording information presented by the physician, asking questions, providing information about the patient to the physician, participating in deliberations about the treatment options presented etc). More conceptual and empirical work is needed to help define and describe what STDM means in this broader interactional context.

In summary, there are several important conceptual issues that still require attention in order to be able to clearly and consistently define what we mean by STDM. Until we know what we mean by this concept, trying to implement STDM as part of routine practice remains problematic.

ii) Do Variations in Patient and Physician Preferences for STDM Exist?

STDM is increasingly advocated as a kind of ideal way to make treatment decisions. However, empirical studies show that some patients prefer that their physician make the treatment decision^(2,3), and there is nothing inherently wrong with this preference. Also some physicians may not feel comfortable sharing the decision making process⁽²⁹⁾ and both parties (physicians and patients) must agree to this approach if it is to be implemented voluntarily in any given encounter. Some patients may prefer to make the decision on their own or with family and friends rather than with the physician (the informed approach), and some patients may prefer an in-between approach. Interestingly, there has been less research attention paid to the informed approach to treatment decision making (compared with STDM) and to exploring the positive and negative impacts of the former on a variety of outcomes. This may be because there is some confusion in the literature as to whether these two approaches are one and the same or different. (See Charles, Gafni & Whelan^(6,7) for a discussion of their differences).

The alleged merits of STDM and DA have become so widely endorsed that several United States state governments are considering or have passed legislation to promote further research, demonstration projects and more widespread implementation of these initiatives⁽³⁰⁾. One state (Minnesota) considered (but ultimately rejected) passing legislation that would have required patients enrolled in public programs to participate in a patient-centred decision making processes before providers could be reimbursed for surgeries for a number of conditions⁽³¹⁾. Even the suggestion to mandate implementation of STDM seems problematic in light of both definitional differences in what this term actu-

ally means and how to implement this approach, and in light of research evidence suggesting that there are differences in patient and physician preferences for involvement in treatment decision making. Given this finding and the possibility that patient preferences might be formed and even change several times during a single medical encounter, advocating STDM for widespread routine use in clinical practice seems misguided, whatever good intentions lie behind this endorsement.

Also the meaning and appropriateness of STDM in different cultural contexts is still a relatively under researched area and little is known about the fit between shared approaches to treatment decision making, including the use of decision aids, and different cultural contexts. Decision aids embody a number of cultural assumptions which are often not made explicit. For example, decision aids are firmly embedded in a biological model of illness, an evidence-based medicine paradigm, and medical concepts of risk. These beliefs reflect a purely "technical" or "clinical" approach to decision-making and downplay the influence and significance of other factors, including cultural beliefs⁽³²⁾.

The use of decision aids also reflects a cultural emphasis on the autonomy of the individual in decision making as opposed to a broader social framework within which to view this process^(33,34). These common features of decision aids are not surprising, given the clinical and research contexts in which they have been developed. But we wonder to what extent such tools are appropriate for patients from different cultural groups and how sensitive such tools are to the values of different cultural groups. We also wonder to what extent these cultural issues have been addressed in either the research development phase of decision aids or their implementation and evaluation. Even such basic issues

as the range of treatments considered appropriate to include as options and the type of information considered relevant to evaluate options may vary depending on cultural beliefs.

iii) What Outcomes Can and Should STDM and /or DA be Expected to Achieve and What is the Relationship Between Them?

Since the early 1990's decision aids have been advocated as a tool to help physicians involve patients in the treatment decision making process, i.e., to promote and facilitate STDM and to create more informed patients. Over time, however, the conceptual link tying the use of decision aids to the facilitation of STDM has become more blurred. In some cases, the term decision aid is now talked about as if it is synonymous and interchangeable with the term STDM, and similar outcomes tend to be measured. In other cases, interest in the impact of decision aids on patient outcomes is seen as an important research topic in and of itself overshadowing the question of what role decision aids can play in different approaches to treatment decision making. In fact, some goals have been defined for decision aids that go well beyond a role in promoting STDM, as we will discuss below.

Like the concept of STDM, definitions of the term decision aids vary, with some definitions focusing on the role of decision aids in conveying information to patients on the benefits and risks of various treatment options⁽³⁵⁾ and other definitions focusing on the role of decision aids in improving the quality of decisions, with decision quality defined as "the extent to which patients choose and /or receive health care interventions that are congruent with their informed and considered values"⁽³⁶⁾. Whether decision aids should be expected to elicit

and measure patient preferences, and if so, how, is a controversial topic and we have discussed this issue in more detail elsewhere Charles, Gafni & Whelan⁽²¹⁾.

The number and range of outcomes that decision aids are expected to achieve has also grown over the last decade, and are somewhat controversial^(21,37). These measures fall into different conceptual categories. One major category of outcomes relates to information transfer and includes such measures as the extent of patient knowledge and understanding of treatment risks and benefits^(20,38-40). Another category of outcomes relates to the impact of decision aids on the decision making process and on the treatment decision, including, the extent to which patients want to participate in the process, the specific decision made, satisfaction with the decision making process and with the decision^(41,42). A third category of outcomes relates to the psychological impact of decision aids on, for example decisional burden, decisional conflict and decision regret⁽⁴³⁻⁴⁶⁾. A fourth category of outcomes relates to health status and includes the impact of decision aids on various measures of health status and quality of life⁽⁴⁷⁻⁵¹⁾. More recently several systematic reviews of DA Impact^(35,52). Finally the effects of decision aids on overall health-care system costs have been measured by examining the global financial impact of changes in individual patient's treatment choices (either to more expensive or less expensive treatments) after using some form of decision aid⁽³⁷⁾. The financial cost of actually using a decision aid in the medical encounter in terms of time required to administer the instrument has also been of interest⁽⁵³⁾.

Our concern with the above list is that all of these outcomes are being studied, not necessarily because they reflect our best thinking about what are the most appropriate goals that decision aids

can be expected to achieve, but rather because these are the outcomes that many researchers claim they can measure. We feel that the rationale for the selection of specific decision aid goals needs to be thought through prior to the selection of specific outcome measures; the selection of goals should drive what is measured and not the other way around. Yet empirical studies evaluating the impact of decision aids often report on specific outcome measures without linking these to any specific goals defined for the decision aid they are studying or exploring what mechanisms are hypothesized to link a particular decision aid design feature to a particular outcome. This makes replication of the potentially desirable feature in future decision aids problematic.

In the Charles, Gafni & Whelan^(6,7) conceptual framework defining STDM, DA are seen as a tool to convey information to patients about treatment options and their benefits and risks (as part of the information exchange stage of the decision making process) and not as a tool to achieve other broader goals^(6,7). Even in relation to this one goal, there is still important research that needs to be undertaken to explore i) the extent to which patients understand the information as intended (rather than simply recall the numbers presented) and ii) the extent to which this information is made personally meaningful to the individual patient in his/her decision making process (i.e. *what does this mean for me?*).

Recently in the United States emphasis has been placed on promoting STDM as a means of achieving two system level goals: reducing practice variations and reducing health care costs⁽²²⁾. These goals would only be met if patients consistently chose the same treatment option and the one that is less expensive than the others offered. But it is not clear why the practice of STDM is seen as an appropriate policy instrument to achieve this goal. (The

question of whether these are appropriate goals is another issue). Underlying the concept of STDM is the concept of patient choice. If the policy objective is to reduce practice variations and health care costs, then why offer choice in the first place? This policy initiative seems to reflect the cooptation of a popular patient centred movement (STDM) originally intended to promote patient choice (regardless of the cost implications of patients' choices), in order to achieve unpopular health care system level goals, whose very success, ironically, depends on the unrealistic assumption that patients will always voluntarily restrict their treatment choice to the less costly treatment alternative. (See Charles, Gafni, Whelan et. al., 2005⁽²¹⁾ for a detailed discussion of this assumption).

iv) What Criteria Should We Use to Evaluate the Development, Content and Effectiveness of Decision Aids?

Over the last decade, the growth in the number of DAs has been dramatic. According to Elwyn, O'Connor & Stacey et. al.⁽²⁴⁾, by 1999, approximately 15 patient DAs had been developed in academic institutions but by 1996, more than 500 existed, produced largely by a mix of not for profit and commercial organizations⁽²⁴⁾. The design of a DA (i.e. the way in which information on treatment options, their potential benefits and side effects is communicated to a patient) can have a marked impact on a patient's understanding of treatment options and on her treatment decision. However, until recently, there was no consensus on the most credible criteria by which to evaluate these tools. To help fill this gap, an International Patient Decision Aids Standards (IPDAS) Collaboration was developed⁽⁵⁴⁾.

The Collaboration consists of an international group of researchers, patients,

health practitioners and policy makers. Over several years, the Collaboration has worked to develop a criteria based checklist for evaluating “the development, content and effectiveness of decision aids”^(24,55). An instrument derived from this criteria-based checklist and designed to measure the quality of patient DAs (the IPDASi) was also developed by this Collaboration and is currently being offered for use in DA assessments^(55,56).

While the intent of this International Collaboration was positive, i.e., to bring some standardization, coherence and a certain threshold of quality to the development and evaluation of decision aids, the results of the development process, the list of quality criteria can be challenged. (The full checklist of specific domains covered and specific criteria within these can be found at: <http://ipdas.ohri.ca/resources.html>)

In a recent review article McDonald, Charles & Gafni⁽⁵⁷⁾ explored the available evidence and theoretical (conceptual) support used by members of the IPDAS Collaboration to justify the inclusion of the specific quality criteria found in the domain on presenting to patients probability information on treatment benefits and risks. McDonald et. al., found substantial gaps in the amount of empirical and/or theoretical support identified to justify inclusion in the checklist of these criteria.

Pressure is growing to use these criteria to evaluate decision aids and, on this basis, to differentiate between those that are found to meet a threshold quality standard from those that are not, and to offer certification to those decision aids meeting this threshold. This sense of urgency to implement a universal set of standards risks premature closure on further discussion about the theoretical and scientific justification for these criteria in the first place. Once these criteria are widely used as a gold standard to evaluate

decision aids, they will have a powerful role in shaping the future development and content of decision aids internationally, as well as in legitimizing some forms of DA and delegitimizing others.

Because of these implications, stronger empirical and theoretical support is needed in order to justify promoting or, even more strongly, mandating the use of such criteria for evaluating and certifying decision aid quality. In addition, whether one set of standardized criteria is sufficient for evaluating the development, content and impact of a wide variety of decision aids internationally, or whether a more tailored approach to meet local clinical and cultural contexts may be more appropriate in some situations needs to be further explored.

Discussion

Breast cancer support groups and women with breast cancer were early advocates of increasing the opportunities for patients to participate in treatment decision making within the context of the medical encounter. In response, researchers began to try to define the meaning of a shared approach to treatment making that would provide greater involvement for patients and to develop tools such as DA to facilitate use of this approach in clinical practice. Now, it seems that STDM and DA are advocated for a wide variety of clinical contexts and are promoted as being able to solve multiple problems above and beyond communication issues found in the medical encounter. In recent years, research and advocacy interests have merged such that some researchers in this field are also strong advocates for implementing STDM and/ or DA on a wider basis and are involved in activities to further this end.

We think it is premature to advocate and support wide scale implementation of STDM and DA in order to achieve broad

system level goals that they were never intended to achieve. STDM approaches and DA were developed in the context of the physician patient encounter to improve physician patient communication. We think there is a need to refocus our attention on this original context and recognize that STDM is not for everyone. Rather, patients and physicians can decide to use this approach but they have to understand first what it is, and they have to voluntarily agree that this approach is agreeable to both parties in any given clinical encounter. Moreover, there is no one formula that can be taught to physicians for implementing STDM – no prescription as to how to do it. While the Charles et al framework describes necessary steps for both physicians and patients to follow in a shared process, the authors recognize that implementation of these steps can take a variety of forms, depending on the individuals involved and the particular clinical context.

Charles et al.⁽⁷⁾ also recognize that decision making is a dynamic process which can evolve and change even during a single encounter. This implies that physicians need to be flexible and ready to change their approach if the patient in front of them expresses a desire to become more or less involved in decision making as the encounter progresses. (For examples of how this might occur, see Charles, Gafni & Whelan⁽⁷⁾). All of this suggests that trying to promote implementation of STDM into routine practice as an unquestioned good at this time may cause more harm than good. If STDM and DA fail to achieve all the goals set for them, these concepts and/or their premature implementation will be blamed, risking repudiation of the basic ideas themselves.

As the number and range of goals defined for DA expands, the perceived need for criteria to assess the quality of DA design, content and implementation has also grown. But the promotion and

implementation of the internationally developed IPDAS standards for assessing DA and for possible certification also seems premature. First, the goals defined for DA are expanding and there is as yet no consensus on what these should be, so that developers of criteria face a constantly moving target. Second, stronger theoretical and empirical support for the suggested quality criteria should be established before endorsement of these for quality improvement and possible certification purposes. Third, it is not clear that a single uniform set of standards can be applied to assess the quality of different types of decisions aids in different clinical and cultural contexts and with potentially different goals underlying their development.

In conclusion, we suggest the need for caution, for more thoughtful analysis, and additional research on the challenges raised above prior to endorsement of STDM and DA in routine practice. This would involve a systematic, step by step attempt to address current unresolved issues raised in this paper in order to make implementation more feasible in clinical contexts where both patients and physicians freely choose this approach to making treatment decisions.

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