Design and Testing of Tools for Shared Decision Making

Daniel D. Matlock, MD, MPH; Erica S. Spatz, MD, MHS

Shared decision making (SDM) is grounded in a compelling theoretical framework that ideally helps patients make decisions that are informed and concordant with their goals and values. Yet operationalizing SDM within routine clinical care remains an important challenge. Several approaches have been studied to improve SDM; such strategies include educating clinicians on communication techniques, using a multidisciplinary medical team, incorporating trained decision coaches, and using tools to support patients in their decision making. These tools, commonly referred to as patient decision aids (PtDAs), have garnered the most interest in operationalizing SDM. Accordingly, this article will focus specifically on the development and testing of PtDAs highlighting some important key points (see Box).

Extensive work has been undertaken by the International Patient Decision Aid Standards (IPDAS) collaboration to provide guidance in this arena. Founded in 2003, IPDAS aims to “enhance the quality and effectiveness of PtDAs by establishing an evidence-informed framework for improving their content, development, implementation, and evaluation.” This article will draw on the extensive work of the IPDAS collaboration to describe a 4-step development process for those interested in developing PtDAs, which includes: step 1: understanding the decision; step 2: drafting the first version of the decision aid; step 3: iteratively modifying the tools; and step 4: testing the decision aid in a real-world setting. Additionally, we will discuss potential opportunities to expand the work of the IPDAS collaboration to improve uptake of the PtDA in the clinical setting.

Development and Design of Decision Aids

Several theoretical frameworks have been used in the development of PtDAs. Common theories used by developers include the behavioral decision framework, expected utility theory, decision conflict theory, differentiation and consolidation, fuzzy trace theory, and image theory. Although a complete discussion of decision-making theory is beyond the scope of this article, an excellent summary of major decision theories and their implications on decision aid design were recently summarized by the IPDAS collaboration. One commonly used PtDA development framework that is based on several of these theories is the Ottawa Decision Support Framework. This framework states that participants’ decisional needs (eg, knowledge, values, support) will affect the decisional quality (informed, values concordant decisions), which ultimately impacts subsequent outcomes such as emotions (regret, blame), behavior, and appropriate use of health services. Recently, some developers have argued that development should include a more active and iterative process using end-users in all phases of the development.

These developers have used a participatory action research framework in which both patients and clinicians participate in tool development during real-world clinical encounters with embedded researchers, making modifications based on observations of how the tool is ultimately used.

Regardless of the approach, developers of PtDAs should aim for 3 main attributes: (1) correct and accurate content, (2) readability and usability, and (3) acceptability and lack of bias. Table 1 outlines a typical PtDA development process. The fourth attribute is ensuring that the PtDA is effective in improving the quality of decisions. Effectiveness of PtDAs is the topic of a separate article in this series. Throughout the development process, developers should draw on the expertise of a multidisciplinary team. The team might consist of (but is not limited to) patients, clinicians, and experts in evidence synthesis, information technology, health literacy, and graphic design.

Step 1: Understand the Decision - What Do the Data Suggest About the Risks and Benefits of the Decision Options; What Is the Context of the Decision for Which the PtDA Is Being Developed?

Step one is to gather information about the decision for which the PtDA is being developed. Because PtDAs aim to present information to patients who are actively making decisions, a deceptively complex question then is what data belong in a decision aid? Too little information or the wrong information will not help the decision maker, and too much information may be overwhelming. Before embarking on a full-scale development process, one should check to determine whether a PtDA has already been developed. A useful resource is the University of Ottawa A–Z inventory of patient decision aids (http://decisionaid.ohri.ca/АЗinvent.php) where developers can register their decision aids and have them evaluated using IPDAS scoring criteria. To determine the relevant content, PtDA developers should review the literature regarding the risks and benefits...
KEY POINTS OF THE ARTICLE ON DECISION TOOL DEVELOPMENT

- PtDAs should be used in conjunction with a conversation with a clinician.
- Helping patients consider and clarify their values around a decision is what makes a PtDA different from an information pamphlet.
- Development is iterative, and the key tasks are to make sure the information is understandable, accurate, and unbiased and that the tool fits the needs and workflow of the end-users.
- Trials designed to test the effectiveness of a decision aid need to consider both the patient’s and the clinician’s experience with the tool.
- Decision aids should be living documents that will require updating when new information arises.

of all possible choices, and this information should be summarized in a background evidence document or in a systematic review.18 This background evidence document becomes important when users begin reviewing the decision aid, as the data presented are often a source of contention. Also, the medical literature frequently contains articles with divergent results, and developers will need to decide what data to present in the PtDA. In the case of implantable cardioverter-defibrillators, there are many conflicting studies about the risks, some of which are related to the different definitions of risk and different time frames for follow-up.20 Furthermore, some data originate from randomized, controlled trials (RCTs), and other data originate from observational studies. In general, the benefit of a therapy is most easily derived from an RCT, whereas one can argue that real-world risks may be more accurately derived from an observational study.20 However, these decisions are complicated, and stakeholders often disagree on what data should be presented in a PtDA. Regardless of the source of information, the PtDA will need to be routinely reviewed and updated to ensure that it is consistent with current evidence.

In addition to a comprehensive literature review, PtDA developers should gain a deeper understanding of the decision-making needs and experiences of the participants involved. This can be accomplished through strategies ranging from surveys to in-depth interviews to observed encounters. This process is essential and will allow the developer to gain a deeper understanding of the context in which the PtDA will ultimately be implemented. In the case of implantable cardioverter-defibrillators, many issues were learned from the qualitative needs assessment that would never have been understood through a literature review alone (eg, the importance of guidelines, the influence of device recalls, the lack of understanding about deactivation, and the importance of discussing inappropriate shocks and driving a car).21

Step 2: Developing a First Draft of the PtDA

At some point in the information-gathering process, the developer will need to draft the first version of the PtDA. The initial approach needs to consider 2 key questions in tandem, as 1 will inform the other: (1) what type of tool to develop, and (2) when to introduce the PtDA in the clinical pathway. Current PtDAs come in many forms, including article, videos, websites, and even scripted telenovelas.3,22 Each of these forms has been shown to be helpful in supporting decision making, and there is little guidance on precisely which format is best.2 The type of tool should be informed by the needs assessment, the target population, the context of the decision, and the resources available for development as videos and websites are markedly more expensive to develop. Developers additionally need to consider when in the decision-making process to introduce a PtDA, that is, before, during, or after the clinical encounter. Implementation of the PtDA may be based on feasibility and cost and ultimately guide the type of tool developed. For example, if the intention is for a PtDA to be viewed before a clinical encounter, then a web-based tool may be more or less ideal depending on the target populations’ access to and comfort with computers. Table 2 lists the advantages of several common types of tools that have been developed.

The next question faced by a decision aid developer is what to put in the PtDA? The IPDAS collaboration provides guidance. Although each decision is different and the actual content of the PtDA should ultimately be determined by the literature review, needs assessment, and iterative participant testing, the IPDAS checklist serves as a useful guideline for drafting the initial PtDA.3 The IPDAS includes the following 4 main domains: (1) What is the decision? (2) What are the risks/benefits? (3) What are the important values to consider

Table 1. Steps of Decision Aid Development

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<thead>
<tr>
<th>Step 1 – Understand the decision</th>
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<tr>
<td>1. Literature review: Aggregate the appropriate data (effectiveness and risks) surrounding a given intervention and summarize in a formal document.</td>
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<td>2. Needs assessment: Determine what patients and clinicians think are important attributes of the decision. This process is often done through qualitative interviews or written surveys.</td>
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<tr>
<th>Step 2 – Develop the initial draft of the decision aid based on user input in step 1</th>
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<tr>
<td>1. Determine the type of tool that would be useful and feasible for the given decision situation (video, article, web-based, etc)</td>
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<td>2. Consider when to introduce the PtDA in the clinical encounter (before, during, or after) because this may influence the type of tool developed</td>
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<td>3. Use the IPDAS criteria as a guide for what to include in a decision aid. At a minimum, the tool should:</td>
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<tr>
<td>a. Identify a decision that needs to be made</td>
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<td>b. Describe the risks and benefits of all options</td>
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<td>c. Assist people in clarifying their values, either explicitly or implicitly</td>
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<td>d. Empower the person regarding the next steps in the decision-making process</td>
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<th>Step 3 – Iteratively modify the tools with end-users</th>
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<td>1. Test the tool with all end-users, including patients, clinicians, and any other potential participants (eg, caregivers) who have a relevant role in the decision making as determined by the needs assessment</td>
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<tr>
<td>2. Modify the tool with the goal of improving accuracy, understandability, and balance</td>
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<th>Step 4 – Pilot test and/or implement the tool in a real-world setting</th>
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<td>1. Researchers can choose from several study designs, including randomized, controlled trial of patients, clustered randomized trial of clinicians or clinician groups, and before and after study comparisons</td>
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<tr>
<td>2. Each study design has advantages and disadvantages</td>
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IPDAS indicates International Patient Decision Aid Standards; and PtDA, Patient Decision Aid.
Table 2. Advantages and Disadvantages of Different Patient Decision Aid Formats

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<tr>
<th>Format</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Short, article decision aids</td>
<td>- Short article decision aids may have more success in implementation within a clinical encounter.</td>
<td>- These tools tend to not be comprehensive and are thus unable to meet all of the IPDAS criteria. However, whether all the IPDAS criteria are necessary to achieve decision quality is a topic of debate.</td>
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<td>Examples: Option grids (<a href="http://www.optiongrid.org">www.optiongrid.org</a>), Statin choice article decision aid – Mayo clinic</td>
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<tr>
<td>Longer article decision aids</td>
<td>- Easy to modify and update.</td>
<td>- Difficult to implement during a clinical encounter. Ideally, these tools would be delivered to a patient before or after a discussion with a clinician.</td>
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<td>Examples: AHRQ booklets, Ottawa decision aids</td>
<td>- Inexpensive to develop.</td>
<td>- Often require higher literacy levels.</td>
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<td>Video decision aids</td>
<td>- May be more useful to populations with lower health literacy.</td>
<td>- Costly to develop.</td>
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<td>Examples: Health Dialog Tools, ACP Decisions</td>
<td>- Can include patient vignettes.</td>
<td>- Visual images may influence decisions in ways not intended by the developer.</td>
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<td>Web-based decision aids</td>
<td>- Can be interactive.</td>
<td>- Development and modification require technical expertise which can be costly.</td>
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<td>Examples: Healthwise tools, Bresdex.com</td>
<td>- Can be linked to electronic medical records and tailored to patient characteristics.</td>
<td>- Patients must have access to the Internet.</td>
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<td>ACP indicates Advance Care Planning; AHRQ, Agency for Healthcare Research and Quality; and IPDAS, International Patient Decision Aid Standards.</td>
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Step 3: Iteratively Modify the Tools With Potential Participants

After the initial prototype is developed, the tool should be tested and modified iteratively with end-users including patients, clinicians, and any other potential participants (eg, caregivers) who have a relevant role in the decision making as determined by the needs assessment. Throughout the testing, the tool should be modified based on the input from the participants to ensure that the tool is accurate, understandable, and as balanced as possible. Achieving balance can be difficult, particularly as opinions vary between patients and clinicians.

Step 4: Testing the Tool in a Real-World Setting

Once the tool is developed, consideration must be given to the study design, setting, and implementation of the PtDA. Table 3 outlines some potential study designs and their strengths and weakness as applied to decision aids. Randomized, controlled trials are traditionally perceived as the most rigorous study design to minimize bias and potential confounders. However, the dyadic or multidisciplinary nature of shared decision making creates some inherent limitations to randomized trials. If randomization occurs at the patient level, the same clinicians will be engaging with patients in both the decision aid and the usual care arms, increasing the probability for spillover. In spillover, clinicians may adopt language or processes from the decision aid into their routine practice, thereby diluting differences between the intervention and usual care groups. The majority of trials in the Cochrane review of decision aids were patient-level randomized trials. Clustered randomized trials are particularly important for decision aids that are designed to be used within a clinical encounter. A cluster randomized trial design offers an attractive alternative to avoid the effects of spillover seen in patient-level trials. In clustered randomized trials, clinicians or an entire clinician group are randomized to either use of the decision aid or to the control with the idea that all patients seen by a clinician or a clinician group will receive the same care. Randomizing at the clinician level may not completely avoid spillover because clinician styles are often influenced by colleagues and cultural norms, which may evolve as the intervention is implemented. For this reason, it may be preferable to cluster by clinician group for trials of decision aids and not clinician. The downsides of clustered randomized trials primarily relate to resources and logistics. Outcomes are assessed at the level of the group; hence, the sample size is considerably lower than had randomization occurred at the level of the patient, which may reduce statistical power from which to draw conclusions. An alternative approach is to assess outcomes at the patient level; however, patients with similar characteristics tend to cluster around clinicians and clinician groups, which may overestimate differences between groups.

Because of the limitations and challenges involved in performing randomized, controlled trials, several researchers have used quasiexperimental, pre/poststudy designs, whereby a historical control period is followed and compared with a
period of PtDA implementation and evaluation. This design is efficient and less costly, and the characteristics of the patient population tend to be stable. One limitation of a pre/poststudy design is not having a concurrent control group, and thus being vulnerable to secular trends, for example, changes in attitude toward the intervention or new data, which may influence outcomes. Additionally, priming may occur, whereby responses to survey items are influenced by experience with the topic and question. For example, assessment of clinician behavior during the control or usual care study period may show that clinicians perceive themselves as always including patients in the decision-making process. However, after the implementation of the PtDA, clinicians may newly recognize and report that they do not regularly engage patients in this type of shared decision-making process, despite adoption of the PtDA in their practice. A recent example of this is the before and after evaluation of the Patient Refined Expectations for Deciding Invasive Cardiac Treatments (PREDICT) tool for patients considering percutaneous coronary intervention options.28

Researchers must also decide on the appropriate setting in which to introduce a decision aid. Presumably, there is a sweet spot, the period between the patient being presented with a choice and the point at which a decision needs to be made.29 This is the ideal time for a decision aid. Because PtDAs require patients to contemplate their values, consider alternatives, and often make complex decisions, it is important to identify clinical milestones/windows or opportunities where decision making can most easily occur.30 The ideal clinical milestone is not always obvious. If the PtDA is introduced during an acute change in health status (eg, during an acute myocardial infarction or heart failure exacerbation), the patient may not be prepared to engage in a decision-making process. On the contrary, the decision needs to be timely and relevant to the patient to carry import. Consider, for example, a PtDA on left ventricular assist device (LVAD) implantation for patients with advanced heart failure. If the PtDA is introduced at the time of hospitalization for an acute exacerbation, when the decision to implant an LVAD is the difference between life or death, patients may be too sick to engage in a shared decision-making process or may experience decisional regret if they allowed their emotional state, as opposed to their values, to influence their decision.31 The outpatient setting, when patients are stable yet have end-stage heart failure, may be more ideal. This is the kind of balance that must be learned early while the investigator is performing the needs assessment.

Related to setting, researchers must determine (ideally through the needs assessment) who is the most appropriate clinician to introduce the PtDA. Should it be a practitioner who has a longstanding relationship with the patient or the surgeon performing the surgery? For example, it is not clear whether the interventionalist or the referring clinician is in the best position to help patients considering a bare metal stent versus a drug eluting stent for percutaneous coronary intervention. For the purposes of research, it may be impractical to disseminate PtDAs to all referring providers. Moreover, it is not clear that interventionalists would accept and carry out decisions with which they were not involved. On the contrary, referring clinicians who have a rapport with the patient may be better able to assess their patients’ values and reflect preferences but may not be as prepared to discuss the risks and benefits of a bare metal stent versus a drug eluting stent.

**Unique Challenges and Future Directions**

Shared decision making in general and PtDAs in particular are an emerging science. As such, there are many unanswered questions and a significant need for future research. Below, we highlight a selection of challenges and controversies among the development community.

**Should Information in a PtDA Be Tailored to the Individual Patient?**

The type and magnitude of risks and benefits associated with each decisional option may vary based on the characteristics of the patient. For example, an older patient with more competing morbidities will likely have a smaller benefit and larger risks for many of the aforementioned therapies. Some argue that patients should be presented with tailored statistics that more accurately reflect their clinical situation.30 This is cumbersome in that it often requires a mathematical model or a host of assumptions to determine which tailored statistics to provide to any given patient. Whether individual patient decisions are sensitive to this tailoring is unknown.

**Can Emotion and Affect Be Addressed in a PtDA?**

Much of the work on decision aid development has focused on the cognitive transfer of information. However, many major decisions are largely driven by emotion, particularly decisions involving tradeoffs around quality versus quantity. This affect heuristic has been shown to influence many cognitive aspects of decision making.32 For example, we found that many patients who were hospitalized in an intensive care unit dying of heart failure were unable to cognitively weigh the risks and benefits of an LVAD because of their overwhelming fear of dying.31 Should PtDAs in this setting be designed to address emotions like fear, and, if so, does this help patients to make more cognitive decisions?

**Are PtDAs Useful for Chronic Disease Models, in Which Patients Make Multiple Decisions Over Time?**

Traditionally, PtDAs have been conceived and developed to assist discrete decisions. However, the vast majority of medical decisions are made by patients with chronic illness who often have to make multiple, repeating decisions during a long period of time. For example, patients with heart failure may frequently need to recalibrate decisions about activity, salt intake, and medications. Can PtDAs be developed to help patients with recurring decisions such as these? Should PtDAs be used periodically in patients with chronic illness as a means of reassessing goals of care and ongoing management? At present, the majority of PtDAs focus on discrete decisions rather than the multiple decisions that are made over time, and this area is ripe for research and innovation.

**Conclusion**

The aim of this discussion was to provide a framework for potential developers to consider in developing PtDAs.
However, this field is ripe for innovation, particularly in the areas where decisions are more difficult. At present, PtDAs are stymied in the research setting. Whether their lack of adoption into routine clinical practice stems from poor development, reluctance on the part of clinicians to use them, prohibitive workflow, maligned incentives, or inaccessibility at the time they are needed is not clear. Certainly, essential step toward a solution to this problem is to invite all potential stakeholders (patients, clinicians, clinical staff, administrators, etc.) into all aspects of development. With increasing interest among healthcare leaders, policymakers, and funders to bring PtDAs into the fold, there may be more opportunities to study the development, uptake, and impact of PtDAs. Such investigation is critical to informing best practices for developing PtDAs and policies to support their use.

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None.

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