Quality patient decision aids to support healthcare decision making

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Abstract

This article describes the development and use of quality patient decision aids to support patient involvement in making healthcare decisions. Briefly, patient decision aids should provide at least information on options, benefits, and harms, and help patients clarify their values for outcomes of options. The International Patient Decision Aid Standards provide guidance on developing, evaluating, and implementing quality decision aids that minimize the risk of biased decision making. Combining these standards with the related Standards for UNiversal reporting of patient Decision Aid Evaluation studies (SUNDAE), authors of articles on patient decision aids can ensure clear, concise, and understandable reporting.

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What are patient decision aids?

Over the last 20 years, many health authorities and healthcare organisations around the world have encouraged providing healthcare that is more centred on patients and their families.[1, 2] Patient-centred care provides "care that is respectful of and responsive to individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions."[3]

Patient participation in clinical decisions can, however, be slowed by certain barriers. In particular, patients need to know about their condition and the treatment options and outcomes (benefits, harms); know their personal values and preferences; and believe that they can influence decision making, for example, that they have permission to participate, are confident in

their knowledge, and effective at applying their decision making skills.[4]

Patient decision aids are designed to help patients overcome these barriers and participate more actively in healthcare decisions. A patient decision aid can be defined as:

> *"An aid that supports patients by making their decisions explicit, providing information about options and associated benefits/harms, and helping clarify congruence between decisions and personal values."*[5]

Patient decision aids are available in a variety of different formats, including leaflets, videos, and internet-based tools. Patients can used them before, during, or after face-to-face meetings with their health professionals, or they can use them on their own without any connection to a health professional.[6] The largest database of patient decision aids is Ottawa Hospital Research Institute's A to Z Inventory of Patient Decision Aids.[7]

A Cochrane review of 105 randomised control trials[5] showed that patients exposed to patient decision aids had more knowledge about treatment options, more realistic expectations, less decisional conflict related to feeling uninformed or uncertain about personal values, and more involvement in the decision-making process than patients receiving standard care only. Patient decision aids also reduced the number of patients choosing major elective invasive surgery in favour of more conservative options. Hence, patient decision aids overcome several of the barriers patients have in participating in decision making[4] by increasing knowledge of the condition, options, and outcomes; clarifying patients' values; and providing a structured approach to making decisions.

What is IPDAS?

Patient decision aids can improve uptake of treatment options. This is good when the changes are due to patients' understanding or when patients' values are acknowledged. But this is not good when it is caused by the potential for bias.[8] A concern has been the potential for bias in patient decision aids intended to increase the uptake of specific options.

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To help address this, in 2003, an international collaboration of researchers and key stakeholders (patients, healthcare professionals, and policy makers) developed the International Patient Decision Aids Standards (IPDAS), which are a set of criteria to ensure the quality of the content, development, implementation, and evaluation of patient decision aids.[8] In 2013, the evidence informing IPDAS was updated[9] and the original 74 IPDAS criteria were further revised into a minimum set of 44 criteria,[10] including six items defining what is a patient decision aid, 10 items intended to minimise the risk of bias, and 28 items indicating the quality of a patient decision aid but whose omission would not present a high risk of harmful bias (Table 1). The IPDAS criteria have been adopted by the Washington State Health Care Authority for their programme to certify patient decision aids[11] and by the Norwegian Department of Health for approval of patient decision aids.[12] Further, all patient decision aids in the Ottawa Hospital Research Institute's A to Z inventory have been assessed using the IPDAS criteria.[7]

"Dialysis Choice" – an example of a patient decision aid designed to meet IPDAS criteria

"Dialysis Choice" (Figure 1) is an example of a patient decision aid designed to meet the IPDAS criteria and is included in Ottawa Hospital Research Institute's A to Z inventory of Patient

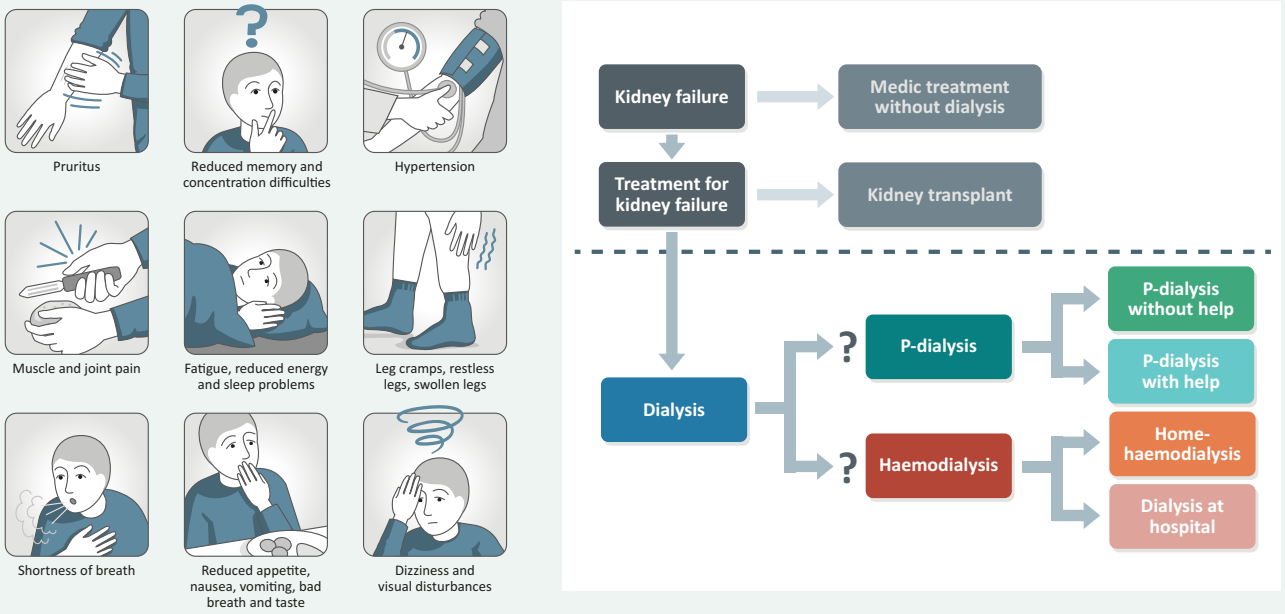

Figure 1. Screen shot from "Dialysis Choice" - decision map and overview of symptoms

Table 1. List of IPDAS criteria [10]

Qualifying criteria to be defined as a patient decision aid

The patient decision aid:

1. Describes the health condition or problem (treatment, procedure, or investigation) for which the index decision is required
2. Explicitly states the decision that needs to be considered (index decision)
3. Describes the options available for the index decision
4. Describes the positive features (benefits or advantages) of each option
5. Describes the negative features (harms, side effects, or disadvantages) of each option
6. Describes what it is like to experience the consequences of the options (e.g., physical, psychological, social) or includes an explicit values clarification exercise

Criteria to minimise risk of bias in the patient decision aid

The patient decision aid:

1. Shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information)
2. Provides citations to the evidence selected (or provides them in an associated document)
3. Provides a production or publication date
4. Provides information about the update policy (or provides this information in an associated document)
5. Provides information about the levels of uncertainty around event or outcome probabilities (e.g., by giving a range or by using phases such as "our best estimate is …")
6. Provides information about the funding source used for development (or provides this in an associated document)

The patient decision aid for screening or diagnostic testing:

7. Describes what the test is designed to measure
8. Describes the next steps typically taken if the test detects the condition or problem
9. Describes the next steps if the condition or problem is not detected
10. Has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias)

Criteria indicating the quality of the patient decision aid

The patient decision aid:

1. Describes the natural course of the health condition or problem if no action is taken (when appropriate)
2. Makes it possible to compare the positive and negative features of the available options
3. Provides information about outcome probabilities associated with the options (i.e., the likely consequences of decisions)
4. Specifies the defined group (reference class) of patients for whom the outcome probabilities apply
5. Specifies the event rates for the outcome probabilities
6. Allows the user to compare outcome probabilities across options using the same time period (when feasible)
7. Allows the user to compare outcome probabilities across options using the same denominator (when feasible)
8. Provides more than one way of viewing the probabilities (e.g., words, numbers, and diagrams)
9. Asks patients to think about which positive and negative features of the options matter most to them (implicitly or explicitly)
10. Provides a step-by-step way to make a decision
11. Includes tools like worksheets or lists of questions to use when discussing options with a practitioner
12. Reports the development process included a needs assessment with clients or patients
13. Reports the development process included a needs assessment with health professionals
14. Reports the development process included a review by clients/patients not involved in producing the decision support intervention
15. Reports the development process included a review by professionals not involved in producing the decision support intervention
16. Was field tested with patients who were facing the decision
17. Was field tested with practitioners who counsel patients who face the decision
18. Describes how research evidence was selected or synthesised (or provides this information in an associated document)
19. Describes the quality of the research evidence used (or provides this information in an associated document)
20. Includes authors'/developers' credentials or qualifications
22. Reports readability levels (using one or more of the available scales, or provides this information in an associated document)
22. Has evidence that it improves the match between the preferences of the informed patient and the option that is chosen
23. Has evidence that it helps patients improve their knowledge about options' features

Patient decision aids for screening or diagnostic testing:

24. Includes information about the chances of having a true-positive test result
25. Includes information about the chances of having a true-negative test result
26. Includes information about the chances of having a false-positive test result
27. Includes information about the chances of having a false-negative test result
28. Describes the chances the disease is detected with and without the use of the test

Decision Aids.[7] The aid is intended to be used by patients with chronic kidney disease to help them choose dialysis options during shared decision making meetings with a dialysis coordinator and with their family at home. The dialysis coordinator is a nurse who is specially trained to deliver the intervention that requires tailoring the decision support and using three different communication skills: mirroring, active listening, and value-clarifying. Dialysis choice includes a decision map and an overview of symptoms to help understand why a choice is being made and which options are available (e.g. peritoneal dialysis versus haemodialysis at home or in the hospital). The goal of the aid is to provide insight into and to foster discussion of the advantages and disadvantages of each option. Further, the aid includes a "values clarification" exercise that asks patients to rate the importance of different option features according to a five-point scale. During meetings with the patient, the dialysis coordinator uses the patient's responses from the decision aid to tailor the support to each of the patient's needs, expectations, and values.

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Dialysis Choice was developed in Aarhus, Denmark, and evaluated in four Danish hospitals. It has since been implemented in three other Danish hospitals.[13-15] In evaluations, Dialysis choice increased patient involvement in decision making and led to choices that reflected patients' values for outcomes of options.[14,15] Using this aid, patients more often chose a home-based than a hospital-based treatment,[13] and those receiving home-based treatments became more involved in their treatment and healthcare over time.[16] Dialysis choice, along with meetings with the dialysis coordinators, were the two active mechanisms contributing to the improved decision making.[14]

The "Dialysis Choice" patient decision aid is publicly and freely available in Danish, English, and Arabic in the A to Z inventory at Ottawa Hospital Research Institute.[7] Based on the IPDAS criteria, "Dialysis Choice" met all defining criteria, all but one criterion to minimise risk of bias (it does not provide references to the scientific evidence used), and most of the quality criteria. In fact, the patients involved in the development process had asked that the sources of evidence not be included in the decision aid.

After using the patient decision aid, one patient stated:

> *"But when you sit there naïve and don't know anything, it [the decision aid] can help a lot. Also that you get more information about it [the decision]."*[14]

After starting home haemodialysis, another patient stated:

> *"Well, they [the decision coach meetings] have contributed to making me realise what I've started. There haven't been any big surprises. Nothing has shocked me. I would even say that the first dialysis session was exciting in some ways, because knowing that I have come this far and now we had to cross to the other side of the road."*[16]

Rapid development of a patient decision aid to help nursing home residents considering a move to their family's home during the COVID-19 pandemic.

In Spring 2020, at the beginning of the COVID-19 pandemic, several outbreaks occurred in Canadian nursing homes. As a result, many families wondered whether they should reduce the older adults' risk of contracting COVID-19 by moving them into their home. However, this decision had several potential benefits and harms that needed to be weighed. A decision aid to support families in making this decision was rapidly developed by a team of experienced patient decision aid developers and healthcare professionals experienced in caring for older adults in Ottawa, Canada.[17] The aid was based on the well-tested Ottawa Decision Aid Template and the Ottawa Personal Decision Guide[18] and developed based on a recent umbrella systematic review, which indicated that patient outcomes did not differ when older adults lived in a private home or nursing home as long as their personal care needs were met.[19] Value statements in the decision aid were developed based on public responses to media releases in the Canadian news focusing on COVID-19 outbreaks in nursing homes. The patient decision aid was developed within two weeks and was endorsed by the National Institute on Ageing of Canada. It was then widely disseminated through Ottawa Hospital Research Institute's the *A to Z Inventory of Patient Decision Aids* and through traditional and social media. It has since been downloaded more than 25,000 times.[19]

User feedback of the decision aid has been positive. For example, one user said:

> *"Thank you to you and your team for putting out resources that will allow families to make informed decisions about their loved ones during this pandemic. My wife, 51, lives with dementia at a long-term care home. I found your document to be most helpful."*[19]

How to involve patients and healthcare professionals in the development of patient decision aids

IPDAS recommend that patients and healthcare professionals participate in the various stages of developing a patient decision aid.[21] This can be done, for example, by asking patients and healthcare professionals what they need to prepare to discuss a decision, reviewing the decision aid by experts (e.g., healthcare professionals, patients) who were not involved in its development, and field testing the decision aid with patients facing the decision and healthcare professionals who counsel patients on the options.[8] More recently, healthcare professionals and patients participate as partners on the research team during the design of patient decision aids.[20] A recent survey of 98 researchers who had used a randomised trial design to evaluate 108 patient decision aids found that co-design by healthcare professionals and patients is important for ensuring that decision aids intended for patients and healthcare professionals fits within clinical practice.[21]

According to a 2021 IPDAS update,[22] development of patient aids should be an iterative process comprising three different phases:

- Understanding the decision making needs of the patients and the healthcare professionals through interviews, surveys, observations, literature reviews, etc.
- Developing the patient decision aid in a collaboration between patients and healthcare professionals, e.g. through multidisciplinary workshops
- Assessing the interactions and experiences of patients and healthcare professionals when using the patient decision aid

Patient and public involvement in research can contribute to development and evaluation of patient decision aids.[23] In the Dialysis Choice

example, both patients and healthcare professionals were involved throughout the research.[24] One patient was particularly proud of the aid and wanted all Danish hospitals to use it.[24] For the COVID-19 location of care example, it was developed so rapidly that only healthcare professionals were included in the small development team. Authors acknowledged the limitation of not involving patients.[17]

How to report research on patient decision aids

Reporting on the characteristics of patient decision aids is currently suboptimal. A review of 17 randomised controlled trials revealed that only 59% of authors reported all IPDAS qualifying criteria. This made it difficult for readers to determine whether the tested intervention was, in fact, a patient decision aid, and few trials described the patient decision aid adequately to determine if the IPDAS criteria for minimising the risk of bias were addressed.[25] Further, the IPDAS update on patient decision aid development[22] does not include an adequate description of the development process, although authors can provide additional details in appendices or other supporting documents.

In 2018, the IPDAS collaboration developed SUNDAE (Standards for Universal reporting of patient Decision Aid Evaluation Studies) for reporting studies evaluating patient decision aids. Two related papers were published, one describing the reporting standards and the guideline development process[26] and the other elaborating on the standards with examples demonstrating their use.[27] The SUNDAE guideline is included in the EQUATOR Network of reporting guidelines, and journals are encouraged to have their authors follow it and acknowledge its use.[28] A search in Google Scholar on May 20, 2021, found that the first paper has been cited 59 times and the second paper 9 times in the first 3 years since their publication. Some journals also require the SUNDAE checklist to be attached as supplementary material. Some studies have supported that the SUNDAE guideline helps ensure adequate reporting of patient decision aids.[15]

Perspectives on using good-quality patient decision aids in healthcare

High-quality evidence indicates that patient decision aids are effective interventions that lack associated harm.[5] However, getting them incorporated into routine clinical practice can be challenging. In the survey of 98 authors of 108 patient decision aid trials, 28% of the authors reported that the patient decision aid was implemented after the trial.[21] Barriers to uptake in the clinic included outdated decision aids

Table 2. Strategies for implementing patient decision aids [29,32]

Focus area	Strategies for implementation
Intervention characteristics	• Keep patient decision aids as simple as possible and use plain language • Establish processes for their use in clinical practice
Clinical practice setting	• If patients have a strong emotional response to a new diagnosis or condition, help them come to terms with the diagnosis so that they will be better able to process the information in a patient decision aid • To identify suitable patient decision aids, health professionals need to assess the patient's decision-making needs • Help the whole team understand the value of patient decision aids and their roles in decision processes (senior leadership, administrative staff, healthcare professionals) • The patient decision aids need to be provided to the patients and to be discussed by both patients and healthcare professionals • Provide continuing education for staff focused on patient decision aids and how to support patients in decision making • Ensure that senior leadership supports and encourages the use of patient decision aids
Characteristics of individuals	• Health professionals who are aware, trained, and motivated to use patient decision aids and understand their intended use • Engage health professionals in selecting the patient decision aid and establishing the best processes for its use • Have health professionals invite and encourage patients to use decision aids • Be aware of potential for significant power imbalances between patients and health care professionals
Process	• Embed patient decision aids early in the process when health professionals initially communicate options to patients • Establish delivery of patient decision aids to all eligible patients • Use patient decision aids within a "learning health system" whereby measured patient decision aid outcomes are monitored and used to inform care as well as quality improvement initiatives

coupled with a lack of funding for updates, reluctance of healthcare professionals to use the aid, and lack of infrastructure support. A recent rapid realist review of 23 implementation studies found that patient decision aids become successfully implemented into clinical practice when their content and application was done in collaboration with patients and healthcare professionals; the whole team was trained; patients were prepared and prompted to engage in decision making; support from management was ensured; and measures to monitor quality of decision making were used.[29] Strategies for implementing patient decision aids are summarised in Table 2.

Use of patient decision aids is supported by several healthcare systems. For example, "Patient Experience in the National Health Service in the UK" recommends the use of high-quality patient decision aids.[30] Also, the US Center for Medicare and Medicaid Services provides reimbursement when a patient decision aid is used for the first lung cancer screening by low-dose computed tomography.[31]

Conclusion

Guidelines are available to help develop high-quality patient decision aids, and evidence indicates that they are effective at improving health decision making. In addition, the SUNDAE reporting guidelines are available for studies describing patient decisions aids, and an international repository of publicly available quality-rated patient decision aids is available through Ottawa Hospital Research Institute's A to Z Inventory of Patient Decision Aids. Further, several countries already have health policies recommending the use of patient decision aids in healthcare services. The next priority is to make their use part of routine clinical practice.

Disclaimers

The opinions expressed in this article are the authors' own and are not necessarily shared by their employers or EMWA.

Conflicts of interest

The authors declare no conflicts of interest.

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