Problem with patient decision aids

Joshua R Zadro ,[1] Adrian C Traeger,[1] Simon Décary,[2] Mary O'Keeffe[1,3]

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[1]Institute for Musculoskeletal Health, Sydney School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia
[2]Tier 1 Canada Research Chair in Shared Decision Making and Knowledge Translation, Centre de recherche sur les soins et les services de première ligne, de l'Université Laval, Quebec City, Quebec, Canada
[3]School of Allied Health, Faculty of Education & Health Sciences, University of Limerick, Limeric, Ireland

Correspondence to:
Dr Joshua R Zadro, School of Public Health, Sydney Medical School, The University of Sydney, Sydney, NSW 2050, Australia; joshua.zadro@sydney.edu.au

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Abstract

Patient decision aids are evidence-based tools designed to help patients make specific and deliberated choices among healthcare options. Research shows that patient decision aids increase knowledge, accuracy of risk perceptions, alignment of care with patient values and preferences, and patient involvement in decision making. Some patient decision aids can reduce the use of invasive and potentially low-value procedures. On this basis, clinical practice guidelines and international organisations have begun to recommend the use of patient decision aids and shared decision making as a strategy to reduce medical overuse. Although patient decision aids hold promise for improving healthcare, there are fundamental issues with patient decision aids that need to be addressed before further progress can be made. The problems with patient decision aids are: (1) Guidelines for developing patient decision aids may not be sufficient to ensure developers select the best available evidence and present it appropriately; (2) Biased presentation of low-certainty evidence is common and (3) Biased presentation of low-certainty evidence is misleading, and could inadvertently support, low-value care. We explore these issues in the article and present a case study of online patient decision aids for musculoskeletal pain. We suggest ways to ensure patient decision aids help patients understand the evidence and, where possible, support high-quality care.

Patient decision aids are "evidence-based tools designed to help patients make specific and deliberated choices among healthcare options".[1] Ideally, patient decision aids are tools intended to be used within the context of shared decision making that foster discussions about evidence, patient values and healthcare preferences. A 2017 Cochrane review of 105 trials[2] found that using patient decision aids increased knowledge, accuracy of risk perceptions, alignment of care with patient values and preferences, and patient involvement in decision making.

Patient decision aids are designed to enhance patient decision making—through improvements in knowledge, decisional conflict and other decision-making outcomes—rather than influence treatment choice. Nevertheless, some patient decision aids have been shown to reduce use of some potentially unnecessary procedures.[2] It is on this basis that clinical practice guidelines[3–7] and international organisations such as Choosing Wisely,[8] have begun recommending the use of patient decision aids and shared decision making as a strategy to reduce medical overuse.

The potential of patient decision aids to improve healthcare is clear. There are, however, fundamental issues with patient decision aids that need to be addressed before further progress can be made. As such, the problems with patient decision aids are:

i. Guidelines for developing patient decision aids may not be sufficient to ensure developers select the best available evidence and present evidence appropriately.
ii. Biased presentation of low-certainty evidence is common.
iii. Biased presentation of low-certainty evidence is misleading, and could inadvertently support, low-value care.

We explore these issues below and conclude with potential solutions to ensure patient decision aids support high-quality healthcare and help patients make truly informed choices.

Guidelines for developing patient decision aids may not be sufficient to ensure developers select the best available evidence and present evidence appropriately

The International Patient Decision Aid Standards (IPDAS) Collaboration (established in 2003) is a world-wide group of researchers, practitioners and stakeholders who share the common goal of continuing to enhance the quality and effectiveness of patient decision aids.[9] As such, IPDAS have developed checklists—through collaborative consensus of participant members—to ensure patient decision aids are developed and reported in a consistent and robust way. Existing IPDAS checklists are comprehensive and regularly updated following synthesis of decision science evidence on how to present information in different ways.[10–12] Nevertheless, there is room to further improve the checklists by providing specific guidance on the type and presentation of evidence to be included in patient decision aids.

Patient decision aids are expected to use the best available evidence from guidelines, systematic reviews and randomised controlled trials to ensure patients truly understand the benefits and harms of different options. However, developers simply focusing on satisfying IPDAS checklists items[9] may miss guidance on the type of evidence that should be included or prioritised in patient decision aids (such guidance is detailed elsewhere[12]). This is problematic because much of the available evidence on benefits and harms is of low certainty.

IPDAS checklists do provide some recommendations for the presentation of evidence, largely based on decision science (ie, research that investigates the decision-making process).[10–12] Recommendations include: 'provide information about outcome probabilities', 'allow the user to compare outcome probabilities across options', 'provide information about the levels of uncertainty around event or outcome probabilities (eg, by giving a range or by using phrases such as 'our best estimate is…')', 'provide references to evidence used' and 'describe the quality of scientific evidence (including lack of evidence)'.[9] However, to ensure patient decision aids present evidence in an unbiased way, developers may require further guidance.

In regard to the presentation of evidence, developers of patient decision aids should include quantitative estimates of benefits and harms (including, where possible, between-group effects from randomised trials), quantitative estimates of benefits and harms from a 'no treatment' or 'wait and see' cohort (ie, moving beyond simply describing 'the natural course of a health condition'), and present the uncertainty of the estimates. The inclusion of this information in patient decision aids will help patients better understand the expected magnitude of benefit (or likelihood of harm) of different options, and understand how certain they can be about these outcomes.[10 13–15] Without this information, patient decision aids could inadvertently encourage particular tests, treatments or procedures based on low-certainty evidence.[14 15] For example, one study found that communicating low-certainty evidence to patients with colorectal cancer (in a hypothetical scenario) increased patient uncertainty about benefits and harms and increased patient worry.[15] Another study found that providing quantitative estimates of benefits and harms for cardiovascular disease medication increased knowledge, led to more appropriate treatment choices and corrected overestimation of benefit.[14]

Biased presentation of low-certainty evidence in decision aids is common

What proportion of patient decision aids clearly describe the quality of evidence, average between-group effects and the uncertainty of the estimates of benefits and harms? To spark thought and further inquiry, we answered this question for patient decision aids developed for patients with musculoskeletal pain (box 1). While biased presentation of evidence could impact clinician decision making, we framed our analysis on the possible impact on patient decision making.

Overall, we found that online patient decision aids for low back pain and knee osteoarthritis present low-certainty evidence to support different test and treatment options in a way that could mislead patients (table 1). Of particular concern was that more than half use low-certainty evidence (when evidence of higher certainty was available) and less than one-third compare quantitative estimates of benefits and harms between different options (between-group effects).

Patient decision aids with biased presentation of low-certainty evidence can also be found for other musculoskeletal conditions[16] and non-musculoskeletal conditions.[17 18] For example, a patient decision aid on physiotherapy versus surgery for shoulder pain did not include a 'no treatment' option or cite high-quality evidence from several recent Cochrane reviews that question the effectiveness of both options.[19–21] A patient decision aid for women with breast cancer ('Should I Have Breast-Conserving Surgery or a Mastectomy?') did not include a 'no treatment' option or report quantitative estimates of benefits and harms.[18] This is despite being labelled as a high-quality decision aid by fulfilling all IPDAS criteria; including 9 out of 9 criteria to 'lower the risk of making a biased decision'. A patient decision aid for men with prostate cancer ('Should I Choose Active Surveillance?') fulfilled all IPDAS criteria but did not compare quantitative estimates of benefits and harms between options or acknowledge the uncertainty of the evidence.[17] Fortunately, we located patient decision aids that fulfil all IPDAS criteria, use high-quality evidence and report evidence for different options in a way that would minimise bias.[22 23]

Box 1 Case study: online patient decision aids for musculoskeletal pain

Musculoskeletal pain, including low back pain and osteoarthritis, is the leading cause of disability worldwide.[27] In light of growing concerns about the inappropriate use of tests, treatments and procedures for musculoskeletal pain,[28] guidelines are increasingly recommending shared decision making (eg, guidelines for knee osteoarthritis,[6] low back pain[7] and shoulder pain[29]). Patient decision aids, tools designed to facilitate shared decision making, have also received increasing attention. Articles in major medical journals suggest that "increasing the availability and routine use of patient decision aids could help patients engage more meaningfully in shared decision making".[30]

A recent study by Fajardo *et al* identified 25 publicly available online patient decision aids for low back pain and knee osteoarthritis.[25] We examined these decision aids to determine the number that: included high-quality evidence, presented average between-group effects from randomised trials, presented expected outcomes without treatment and described the uncertainty of the estimates of benefits and harms. Details of the analysis can be found in online supplementary appendix 1.

The problem with online patient decision aids for musculoskeletal pain…

Less than half of the publicly available online patient decision aids for low back pain and knee osteoarthritis used evidence from guidelines, systematic reviews or randomised controlled trials to inform their estimates of benefits (45%) and harms (35%). Less than half included quantitative estimates of benefits and harms, and of these, many fail to compare effects between different options (40% report between-group effects for benefits; 67% for harms). Only half included a 'no treatment' or 'wait and see' option, and less than 20% acknowledge the uncertainty of the evidence used (table 1).

Biased presentation of low-certainty evidence is misleading, and could inadvertently support, low-value care

Biased presentation of low-certainty evidence is misleading for two reasons:

i. Patients may not understand the reasons for improvement in their condition that are unrelated to the treatment they receive.

Table 1 Type and presentation of evidence in 22 publicly available patient decision aids for low back pain and knee osteoarthritis*

Characteristics	Yes, n (%)
Benefits	
Mentions benefits	22 (100)
Benefits cited	12 (55)
Highest level of evidence cited for benefits (n=22)	
Guidelines, systematic reviews, RCTs	10 (45)
Observational studies	1 (5)
Textbooks	1 (5)
Unclear	10 (45)
Quantitative estimates presented for benefits	10 (45)
Between-group effects	6 (60)
Within-group effects	4 (40)
Harms	
Mentioned harms	20 (91)
Harms cited	8 (40)
Highest level of evidence cited for harms (n=20)	
Guidelines, systematic reviews, RCTs	7 (35)
Observational studies	1 (5)
Unclear	12 (60)
Quantitative estimates presented for harms	9 (45)
Between-group effects	3 (33)
Within-group effects	6 (67)
Overall	
Includes 'no treatment' or 'wait and see' option	11 (50)
Mentions the certainty (or uncertainty) of the estimates	4 (18)

*three patient decision aids from Fajardo et al could not be located online.

RCTs, randomised controlled trials.

ii. Patients could believe the benefits and harms of different options are certain when they are not.

Only presenting improvements for people that receive an intervention ('within-group effects') ignores other reasons a patient might improve and could frame the intervention more favourably than it should be. Take knee surgery, for example, four out of eight online patient decision aids in our analysis that present knee arthroplasty as a treatment option for patients with knee osteoarthritis report outcomes only in those who have surgery and do not include a 'no treatment' or 'wait and see' option. If patients are only told, for example, that 70 out of 100 people that have a knee arthroplasty report improved outcomes (ie, only within-group effects), patients might be inclined to choose surgery. This figure does not account for other reasons for within-group improvement such as natural history or regression to the mean. Patients may make different decisions if properly informed about the benefits of alternatives. If the same decision aid also reported that 60 out of 100 people report treatment success without surgery (or 'no treatment') decision outcomes may be different. Even better, we would suggest the following: 'After knee arthroplasty, an additional 10 people out of 100 report treatment success compared with those who do not have surgery.'

As we have seen, communication about the uncertainty of evidence is not clearly specified in IPDAS checklists. So while patient decision aids improve decision-making outcomes such as knowledge, risk perceptions, congruency between informed values and care choices, and involvement in decision making,[2] patients might have a false sense of certainty about the outcomes they should expect. If only low-certainty evidence is available this could leave patients more uncertain than before they read the decision aid. In these cases, it is important to consider whether sufficient evidence exists to reasonably produce a well-balanced patient decision aid. Unclear communication about the true benefits and harms of various healthcare options could also partially explain why 15 out of 38 studies that assessed decisional conflict in the 2017 Cochrane review failed to find an effect on this outcome.[2] It is our understanding that seven of the 15 studies used patient decision aids in the context of broader conversations about shared decision making. This finding is puzzling and requires a more detailed analysis since the criteria for the Cochrane review stipulate that all studies should report on an intervention using a patient decision aid to foster shared decision making.

Uncertainty produced by patient decision aids may help explain why improvements in decision making outcomes rarely translate into helping patients avoid invasive and potentially low-value procedures, and may even increase them. For example, of the 16 studies in the 2017 Cochrane review on patient decision aids that had elective surgery as an outcome, only three found that a patient decision aid reduced the proportion of participants who had surgery when equally effective, conservative options were available.[2] Further, a recent analysis of 5751 patients with hip and knee osteoarthritis found that patients exposed to a patient decision aid were more likely to have joint replacement surgery (hip: OR=2.6; knee: OR=1.8) compared with patients who had not been exposed.[24]

Another reason why patient decision aids may not help patients avoid unnecessary care is that they might not technically be 'patient decision aids.' Many resources are labelled as 'patient decision aids' when, in fact, they do not include the necessary information to certify as a decision aid or support shared decision making.[25 26] For example 19 of 25 (76%) patient decision aids in the Fajardo review did not meet IPDAS criteria to certify as a patient decision aid.[25]

Solutions

As patient decision aids grow in popularity, it is vital to ensure that, where possible, patient decision aids use high-quality evidence presented in a way that allows patients to compare options fairly. To encourage unbiased presentation of high-quality evidence in patient decision aids, we propose two simple additions to the wording of the IPDAS patient decision aid checklist[9]:

1. Under the existing subheading 'Use up to date scientific evidence that is cited in a reference section or technical document?' include the following statement: 'Use evidence from high-quality guidelines, systematic reviews and randomised controlled trials where possible.' Using high-quality evidence will ensure estimates help patients understand the expected magnitude of benefit, as well as the likelihood of harm of different test and treatment options.
2. Under the existing subheading 'Present probabilities of outcomes in an unbiased and understandable way?' include the following statement: 'Present estimates of benefits and harms in a way that minimises bias, that is, reporting quantitative estimates, reporting between-group effects, including (where possible) outcomes from a 'no treatment' or 'wait and see' option, and acknowledging the level of certainty/uncertainty of the evidence (eg, by using a star system where five stars indicates high-certainty evidence).' Only presenting quantitative estimates of benefits (or harms) for one intervention could bias a patient's decision towards that intervention. Not acknowledging the uncertainty

associated with low-certainty evidence might lead patients to make healthcare decisions that were not truly informed.

Following these criteria could help reduce any unintended consequences of presenting low-certainty evidence in patient decision aids. It may also make decision aids more effective tools to help patients avoid unnecessary tests, treatments and procedures.

Twitter Joshua R Zadro @zadro_josh

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ORCID iD

Joshua R Zadro http://orcid.org/0000-0001-8981-2125

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