



UNIVERSITY OF LEEDS

This is a repository copy of *The International Patient Decision Aid Standards (IPDAS) Collaboration: Evidence Update 2.0.*

White Rose Research Online URL for this paper:
<https://eprints.whiterose.ac.uk/175152/>

Version: Accepted Version

Article:

Stacey, D, Volk, R, Bekker, H orcid.org/0000-0003-1978-5795 et al. (8 more authors)
(Accepted: 2021) *The International Patient Decision Aid Standards (IPDAS) Collaboration: Evidence Update 2.0. Medical Decision Making. ISSN 0272-989X (In Press)*

This item is protected by copyright, all rights reserved. This is an author produced version of an article accepted for publication in *Medical Decision Making*. Uploaded in accordance with the publisher's self-archiving policy.

Reuse

Items deposited in White Rose Research Online are protected by copyright, with all rights reserved unless indicated otherwise. They may be downloaded and/or printed for private study, or other acts as permitted by national copyright laws. The publisher or other rights holders may allow further reproduction and re-use of the full text version. This is indicated by the licence information on the White Rose Research Online record for the item.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.



eprints@whiterose.ac.uk
<https://eprints.whiterose.ac.uk/>

For Medical Decision Making (1500 words maximum)

The International Patient Decision Aid Standards (IPDAS) Collaboration: Evidence Update 2.0

Dawn Stacey

Robert J Volk

for the IPDAS Evidence Update Leads (Hilary Bekker, Karina Dahl Steffensen, Tammy Hoffman, Kirsten McCaffery, Rachel Thompson, Richard Thomson, Lyndal Trevena, Trudy van der Weijden, Holly Witteman)

Corresponding Author:

Dawn Stacey RN, PhD, FAAN, FCAHS, FCAN

Ottawa Hospital Research Institute, University of Ottawa,

451 Smyth Road, Ottawa, Ontario, Canada, K1H 8M5

dstacey@uottawa.ca

Manuscript word count: 1458 words

History of the IPDAS Collaboration

Patient decision aids (PtDAs) are evidence-informed resources to guide patients in the process of making quality decisions.¹ At a minimum, they make explicit the health problem, the decision, provide information on options/benefits/harms, and help patients clarify which benefits and harms matter most.² Optional features in PtDAs are probabilities of outcomes of options, narratives describing patients' experiences with making decisions, and guidance in the process of decision making and engagement with healthcare. They are designed to be used as adjuncts to counseling and are often used to facilitate shared decision making between patients and their clinician. A systematic review of 105 randomized controlled trials demonstrated that compared to usual care, patients exposed to PtDAs have improved knowledge, more realistic expectations, less decisional conflict and participate more actively in making decisions.³ Given that few have been used in clinical practice after trials were completed,⁴ there is increasing research focused on the process used for their development, evaluation, and implementation.

Evidence was emerging in 2003 that PtDAs can affect the uptake of options.⁵ For example, there were decreased hysterectomies and fewer herniated disc surgical procedures when patients were aware of non-surgical options to address the condition. The effect on uptake of options was judged to be positive when PtDAs were unbiased and the change addressed variations in clinical practice.^{6,7} Concurrently, there was concern that PtDAs developed without a guiding set of standards could be used to present biased information.

In 2003, the International Patient Decision Aid Standards (IPDAS) Collaboration was established to enhance the quality and effectiveness of PtDAs by establishing a shared evidence-informed framework for improving their content, development, implementation and evaluation.⁸ The collaboration has been an entirely volunteer organization with no formal affiliation with a

professional society and members have produced a series of evidence-based IPDAS resources (Figure 1 - TBC). IPDAS used an international consensus process to establish the first set of criteria within 12 broad domains for determining the quality of PtDAs.⁶ There was representation from 14 countries with over 100 participants including researchers, clinicians, patients, and policy makers. Based on equi-median ratings of 7 to 9 out of 9, the original IPDAS checklist included 74 items from 11 of the broad domains with a present/absent response scale. The only domain not included was *patient narratives* given the conflicting evidence on narratives and their association with persuasion rather the decision quality. Next the IPDAS instrument for measuring quality was created and validated with only 47 items described on a 4-point scale from strongly agree to strongly disagree.⁹

Given the number of IPDAS items and some challenges with applying the items, IPDAS proposed a minimum set of standards for defining and certifying PtDAs.² There were 127 participants from 16 countries who had some experience with PtDAs who voted on “*if the criterion was not present or of low quality, there would be a risk of harmful bias and potential negative impact on patients’ decision making*”. Considering the numeric and qualitative results from voters, the original IPDAS rating (1 to 9), and comments on feasibility from those trained in using the IPDAS instrument, the expert committee proposed 6 criteria for qualifying to be defined as a PtDA, 6 criteria for certifying PtDAs plus 4 for screening PtDAs (to minimize risk of bias), and others were described as quality criteria. In 2013, IPDAS members published the updated theoretical and empirical evidence on the 12 original broad domains plus one extra team published evidence on implementation of PtDAs.^{1, 10} In addition, to supporting the IPDAS criteria, this update provided more detailed guidance on developing PtDAs, discussed ways of describing the quality of the evidence used to inform PtDAs (e.g. GRADE ratings) and the need

to disclosure actual or potential conflict of interest particularly for funding received from commercial for profit entities used to develop or exclusively distribute PtDAs. The 2013 evidence update did not include changes to the IPDAS criteria at that time.

In 2016, Washington State Health Care Authority launched the first program to certify PtDAs based on the IPDAS criteria.¹¹ The certification program is noteworthy because it provides a heightened level of legal protection to clinicians who use certified PtDAs with their patients.^{12, 13} This program typically announces a call for PtDAs based on specific conditions (e.g., vaginal birth after caesarian, joint replacement) and certified PtDAs are announced on their website. Concurrently, the IPDAS criteria are being used by the Norwegian Health Department for reviewing PtDAs approved for the national platform,¹⁴ the International A to Z Inventory at the Ottawa Hospital Research Institute,¹⁵ and they were proposed for national standards for certification of PtDAs by the National Quality Forum.⁷ The standards are also available in Japanese, Spanish, and Chinese (IPDAS website).⁸

In 2018, the IPDAS reporting guidelines work-group published the Standards for Universal reporting of patient Decision Aid Evaluations (SUNDAE) Checklist.¹⁶⁻¹⁸ Based on the IPDAS quality dimensions and other reporting guidelines, the 26-item SUNDAE Checklist is meant to promote greater transparency and completeness of intervention studies that evaluate patient decision aids.

Given the increased use of IPDAS, rapidly growing number of clinical practice guidelines recommending patient decision aid,¹⁹ and wealth of new research about their use and effectiveness, the IPDAS Steering Committee identified the need for another evidence update with a specific focus on identifying recommendations for changes to the IPDAS criteria.

Strategy for Updating the Evidence about Patient Decision Aids

In Fall 2018, the IPDAS Steering Committee identified 11 team leads for each of the 12 original broad domains with two changes: a) balanced information was merged with presentation of information on options/benefits/harms; and b) delivery of PtDAs on the internet was merged with implementation of PtDAs. Senior researchers were chosen based on their involvement in previous evidence updates and their research in the area of the specific domain. They were encouraged to identify co-leads from another country. Volunteers for each of the domains were recruited through the IPDAS list serve and at the 2018 Society for Medical Decision Making Shared Decision Making special interest group meeting in Montreal, Canada. Concurrently, we asked for other topics that should be included in this update.

Domain teams were tasked with drafting a proposal for the process they planned to use for updating the theoretical and empirical evidence published since the 2013 update and making recommendations of changes to the original IPDAS criteria. Teams were given examples from the 2013 update and asked to create an update of publishable quality. The proposals were reviewed by members of the IPDAS Steering Committee in spring 2019 based on the following criteria: a) names and affiliations of working group leaders and members with representation from two or more countries; b) proposal based on previous IPDAS work including definitions and original criteria; c) proposed methods aim to synthesize the best available theoretical and empirical evidence; d) indication in the proposal that one outcome of Update 2.0 is verifying and/or revising the original criteria with justification for changes; e) timeline aims to have work completed; and f) completed disclosures of interest.

The IPDAS Steering Committee gave careful attention to how potential conflicts of interest would be disclosed among the team leads and members. At the outset of the update,

members were asked to declare direct interests where there was an opportunity for financial gains (income from grants, contract, consulting fees, scholarships, royalties, and patents) for themselves, a spouse or dependent children. Other reportable debts, outside positions, agreements or arrangements, and gifts or travel were also disclosed. Finally, indirect interests where there was an opportunity for benefit for a third party closely associated with the member were also disclosed. Declarations of interest were regathered at the time of release of the updates from all members.

The Current Evidence Update

The update involved **x participants from x countries**. While the IPDAS Steering Committee did not determine any conflicts rose to the point of disqualifying a member from participating in the update, promoting transparency is ongoing priority of the collaboration. The papers in this series on the IPDAS update 2.0 reflect the 11 broad domains. **[add references]** Two of the broad domains published two articles: communicating probabilities about outcomes and health literacy. Other topics suggested for this update were theories and mechanisms, training in shared decision making, application of shared decision making in support of chronic conditions, whether or not to provide probabilities, and targeting specific disadvantaged populations. Given IPDAS's mandate is focused on PtDAs, we excluded suggestions more broadly focused on shared decision making and asked teams to report on updated theories and mechanisms. The other two suggestions were assumed by the *communicating probabilities* team and the *health literacy* team.

Toward Updating the Standards

IPDAS is commonly used to inform the development and evaluation of PtDAs. Evidence continues to support the minimal criteria. A few new criteria were proposed in this update and require a broader consensus process before changes will be made.

References

1. Volk RJ, Llewellyn-Thomas H, Stacey D, et al. Ten years of the International Patient Decision Aid Standards Collaboration: Evolution of the core dimensions for assessing the quality of patient decision aids. *BMC Medical Informatics and Decision Making* 2013; 13: 1-7.
2. Joseph-Williams N, Newcombe R, Politi M, et al. Toward minimum standards for certifying patient decision aids: A modified Delphi consensus process. *Medical Decision Making* 2013; 34: 699-710.
3. Stacey D, Légaré F, Lewis K, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2017. DOI: 10.1002/14651858.CD001431.pub5.
4. Stacey D, Suwalska V, Boland L, et al. Are Patient Decision Aids Used in Clinical Practice after Rigorous Evaluation? A Survey of Trial Authors. *Med Decis Making* 2019; 39: 805-815. 2019/08/20. DOI: 10.1177/0272989x19868193.
5. O'Connor AM, Bennett CL, Stacey D, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2009: 1-118.
6. Elwyn G, O'Connor A, Stacey D, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *British Medical Journal* 2006; 333: 417-422. DOI: 10.1136/bmj.38926.629329.AE.
7. Elwyn G, Burnstin H, Barry MJ, et al. A proposal for the development of national certification standards for patient decision aids in the US. *Health Policy* 2018; 122: 703-706.
8. International Patient Decision Aid Standards. IPDAS versions and use, <http://ipdas.ohri.ca/using.html> (2020).
9. Elwyn G, O'Connor A, Bennett C, et al. Assessing the quality of decision support technologies using the International Patient Decision Aids Standards instrument (IPDASi). *PLoS One* 2009; 4: 1-9.
10. Elwyn G, Scholl I, Tietbohl C, et al. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inform Decis Mak* 2013; 13. DOI: 10.1186/1472-6947-13-s2-s14.
11. Washington State Health Care Authority. Patient Decision Aid Certification Criteria, http://www.hca.wa.gov/hw/Documents/sdm_cert_criteria.pdf (2016).
12. Pope TM. Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law. *The Journal of Law, Medicine & Ethics* 2017; 45: 12-40. DOI: 10.1177/1073110517703097.
13. Fowler FJ, Jr., Barry MJ, Sepucha KR, et al. Let's Require Patients to Review a High-quality Decision Aid Before Receiving Important Tests and Treatments. *Medical care* 2021; 59: 1-5. DOI: 10.1097/MLR.0000000000001440.

14. Helsedirektoratet Norway. Nasjonale Kvalitetskrav til samvalgsverktøy som skal publiseres på helsenorge.no, <https://helsedirektoratet.no/nasjonale-kvalitetskrav-til-samvalgsverktoy-som-skal-publiseres-pa-helsenorgeno> (2017).
15. Patient Decision Aids Research Group OHRI. A to Z Inventory of Decision Aids, Available at: <https://decisionaid.ohri.ca/AZinvent.php> (2020).
16. Hoffman AS, Sepucha KR, Abhyankar P, et al. Explanation and elaboration of the Standards for UNiversal reporting of patient Decision Aid Evaluations (SUNDAE) guidelines: examples of reporting SUNDAE items from patient decision aid evaluation literature. *BMJ Qual Saf* 2018; 27: 389-412. 2018/02/23. DOI: 10.1136/bmjqs-2017-006985.
17. Sepucha KR, Abhyankar P, Hoffman AS, et al. Standards for UNiversal reporting of patient Decision Aid Evaluation studies: the development of SUNDAE Checklist. *BMJ Qual Saf* 2018; 27: 380-388. 2017/12/23. DOI: 10.1136/bmjqs-2017-006986.
18. Volk RJ and Coulter A. Advancing the science of patient decision aids through reporting guidelines. *BMJ Quality & Safety* 2018; 27: 337. DOI: 10.1136/bmjqs-2017-007657.
19. Cochrane Library. *Cochrane Database of Systematic Reviews 2019 Impact Report*. The author, 2020.