International Patient Decision Aid Standards Update (IPDAS 5.0)

This **Policy Brief** summarizes the findings from the consensus process used to make evidence-informed changes to the International Patient Decision Aid Standards (IPDAS 5.0).
Intended audience: policy makers and others who use IPDAS to certify, appraise the quality, and/or develop patient decision aids.

Problem: Patient decision aids (PDAs) are interventions to support patients/public when making healthcare decisions that have more than one option (including wait and see). If poorly developed, there is a risk of PDAs resulting in harmful bias and poor decisions by patients.

How does IPDAS tackle the problem? IPDAS criteria were created as a quality framework for developing and appraising PDAs. In this project, the IPDAS Research Team (including patient partners) answered:

> *Is there international agreement on the proposed evidence-informed changes to the IPDAS criteria from the perspectives of policy makers, patients, healthcare professionals, and researchers?*

What are the key findings? The IPDAS Steering Committee approved the following changes to the IPDAS criteria (against the original 2006 and 4.0 minimal standards versions), that are based on findings from using a 2-step modified Delphi consensus process with 202 voters from 26 countries. Proposed changes were based on the findings from the 2024 Cochrane systematic review of PDAs and the 2021 evidence updates for each of the IPDAS domains. Consensus required 66% agreement on importance of proposed change for each of the 4 voter groups and 66% agreement on essential criteria for reducing the risk of harmful bias.

Qualifying criteria to be defined as a PDA (mandatory)	**Essential criteria** to reduce the risk of harmful bias (must have)
The PDA:	The PDA:
1. Describes the health condition (same) 2. Explicitly states the decision to be considered (same) 3. Identifies the target audience (new) 4. Lists options including if relevant, "wait and see" (e.g., making no change, doing nothing) (revised) 5. Describes positive features of options (benefits) (same) 6. Describes negative features of options (harms) (same) 7. Asks patients to think about which positive and negative features of options matter most to them OR describes what it is like to experience the consequences of options (physical, psychological, social) (revised)	1. Is based on best available evidence that is, where possible, directly applicable to the patients and clinicians using it (new) 2. Describes how potential users were involved in steps of designing, developing and/or refining a prototype (new) 3. Shows negative/positive features of options in a balanced manner (e.g., neutral, unbiased, non-directive, complete) (revised) 4. Reports where the money came from to develop the PDA and it is clearly stated (e.g., plain language, prominent) (revised) 5. Provides complete citations to evidence selected (same) 6. Provides a production or publication date (same) 7. Provides information about the proposed update policy (or available supporting document) (same) Additional criteria for screening decisions: 8. Describes what the test is supposed to measure (same) 9. Describes consequences of a positive screening finding that would not have caused problems if screening had not been done (same) 10. Describes possible next steps based on positive and negative test results (same)

Summary of changes:

- Three criterion types were changed from defining to qualifying, certifying to essential, and quality to enhancing.
- For qualifying criteria, we added 1 new criterion "target audience" and revised 2 criteria.
- For essential criteria, we added 2 new criteria (users involved in development; based on best available evidence) and revised 2 criteria. One criterion was demoted to enhancing "uncertainty around probabilities".
- For enhancing criteria, we added 17 new criteria, revised 9 criteria, and 1 item was removed "allows patients to select a way of viewing the probabilities (e.g., words, numbers, diagrams)".
- 3 new criteria were not approved (give expiration date; use gender neutral terms; use evaluative labels).

Reference: Stacey D, Volk RJ, Smith M, Lewis KB, Carley M for the IPDAS Steering Committee. (March 2025). Policy Brief: IPDAS 5.0. https://decisionaid.ohri.ca/ipdas

What does this mean?

Relevance for populations, settings, and healthcare professionals	The results of this IPDAS 5.0 update are highly relevant to healthcare programs in developed countries given that is where most of the evidence is from on PDAs. PDAs are used with patients in a range of clinical situations for decisions about surgery, medications, location of care, vaccination, and other healthcare treatments. Hence these standards are relevant to PDAs developed for any health-related decision.
Implications for decision-makers	Decision makers and policy makers can use IPDAS 5.0 to determine if a PDA is of high quality and to certify PDAs. IPDAS may also be used to guide PDA development.
Patients and public	Patients and public can use IPDAS to determine if a PDA is of high quality. Patient and public partners are increasingly involved in co-producing PDAs. Project leads could share IPDAS with them to help them understand how the project aims to adhere to these. IPDAS could also be used by patient/public partners to advocate for these standards when they are members of PDA teams.

What other criteria should be considered to improve quality of PDAs?

Enhancing Criteria (desirable but not essential)	
Domains	The PDA…

Presenting balanced information	• Makes it possible to compare benefits and harms for features of available options side-by-side (revised)
	• Describes the natural course of the health condition if no healthcare option is chosen
	• Presents essential content with guidance on how and where patients can seek additional information to support decision making (new)
	Additional criteria for screening PDAs
	  • Describes the chances of disease being found with and without screening
	  • Provides information (including definition) about chances of: true positive test result, true negative test result, false positive test result, false negative test result

Communicating probabilities	• Presents information about outcomes of options (positive and negative) including the chances they [may] happen, if reliable estimates are available • Presents probabilities using both positive and negative frames (e.g., showing both survival and death rates) • Presents probabilities using numbers rather than words in general. Care should be taken if numbers and words are combined (revised) • Presents probabilities using event rates in a defined group of patients for a specified time • Compares probabilities of options using common denominator formats (e.g., probabilities or common denominator (frequencies)) • Uses the same scales in the diagrams comparing options • Describes the uncertainty around the probabilities (e.g., by giving a range or by using phrases such as 'our best guess is') (changed from essential to enhancing) • Uses the same time frame for all options and outcomes, if time-based risk formats are used • Uses visual displays (e.g., icon arrays, stacked bar graphs) that show both the numerator and the denominator (i.e., the part-to-whole relationship) (revised) • Uses risk formats that were tested with end users in the population to whom the risk applies (new)
Clarifying values	• Uses an explicit values clarification method to help patients clarify what it is important to them in deciding upon options (new)
Guidance and decision coaching	• Provides a step-by-step way to make a decision • Includes tools like worksheets or lists of questions to use when discussing options with a health professional
Using evidence-based information	• Indicates which section of the PDA where each citation was used (new) • Reports the source of the personalized evidence, if risk estimates or risk management options are personalized to individual characteristics (new) • Describes how research evidence was searched for, appraised, selected, and synthesized (derived from systematic reviews or evidence-based clinical practice guidelines, where possible) • Describes the quality of the research evidence used (e.g., using the GRADE approach)
Health literacy	• Designed, formatted and written at a level to be understood by its target audience including people with lower health literacy

	• Uses strategies to reduce cognitive burden (e.g., plain language; glossary of key terms; bullet points; simple navigation), by providing non-text ways to help patients understand information (e.g., visual cues and illustrations, audio narration, video) (revised) • Uses field testing to show that the PDA was understood by patients with lower health literacy • Developed in accordance with health literacy guidelines, for example by meeting recommended thresholds of the Patient Education Materials Assessment Tool (PEMAT; >70%) and a grade reading level of 8 or lower (revised) • Reports how co-design was used in its development (new)
Disclosing conflicts of interest	• Reports that the PDA was developed without using money from a source that stands to gain or lose by the choices patients make (new) • Reports that no authors stand to gain or lose by the choices patients make after using the PDA (revised) • Reports that no authors' affiliations stand to gain or lose by the choices patients make after using the PDA (revised) • Includes authors'/developers' credentials or qualifications • Reports where the money came from to copy and distribute the PDA and it is clearly stated (e.g., prominent, written in plain language)
Development	• Includes information about the expertise of the authors/developers (e.g., patients/caregivers, patient advocates, nurses, physicians) • Reports that potential users (e.g., patients, health care professionals, caregivers) were involved in steps to help understand user goals, motivations, needs, and expectations specific to the decision • Involved potential users in steps intended to evaluate prototypes of the PDA • Describes how evaluation showed that undecided patients found the information was presented in a balanced way • Describes how evaluation showed that it was acceptable to potential users • Reports that potential users were observed using the PDA (new) • Uses iterative cycles of feedback from potential users of the PDA (e.g., patients/public, healthcare professionals) in the development (new) • Reports explicit changes between iterative cycles (new) • Includes relevant experts on the development team (e.g., potential users, clinical content/subject matter experts, patients/members of the public who have faced the decision or could reasonably be expected to face the decision in the future, experts in plain language, accessibility, design, engineering, digital security, decision scientists, biostatisticians, epidemiologists, implementation scientists) (new) • Reports that members of equity-deserving populations were meaningfully involved in development of PDA, when relevant (new) • Describes how the PDA was culturally adapted from existing PDAs, where appropriate (new) • Follows a theoretical framework or conceptual model together with IPDAS criteria for development (new)
Evaluation	• There is evidence that the PDA helps patients: - recognize that a decision needs to be made - know about the available options - know about different features of options - understand that values affect the decision - be clear about which features of options matter most to them - discuss values with their health professionals - become involved in decision making in ways they prefer - improves the match between the features that matter most to the informed patient and the option that is chosen • If any evaluation of the PDA was conducted, reports the findings with attention to SUNDAE guidelines (Standards for UNiversal reporting of patient Decision Aid Evaluation) (new) • Describes how evidence of PDA effectiveness was gathered using instruments that have strong psychometric properties (i.e., the evaluation tool is valid and reliable) (new)

For more information, go to https://decisionaid.ohri.ca/IPDAS

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