

Patient decision aid (PDA) certification criteria

Does the PDA adequately:

1. Describe the health condition or problem
2. Explicitly state the decision under consideration
3. Identify the eligible or target audience
4. Describe the medically reasonable options available for the decision, including nontreatment
5. Describe the positive features of each option (benefits)
6. Describe the negative features of each option (harms, side effects, disadvantages)
7. Help patients clarify their values for outcomes of options by:
 - a. Asking patients to consider or rate which positive and negative features matter most to them

and/or

 - b. Describing each option to help patients imagine the physical, social (e.g., impact on personal, family, or work life), and/or psychological effects
8. Make it possible to compare features of available options
9. Show positive and negative features of options in a balanced and unbiased manner
10. If outcome probabilities are included, allow comparison across options using the same denominator
11. Provide information about the funding sources for development
12. Report whether authors or their affiliates stand to gain or lose by choices patients make using the PDA
13. Include author's/developer's credentials or qualifications
14. Provide date of most recent revision (or production)
15. Follow plain language guidelines to ensure understanding of people with low literacy and/or low health literacy skill

Additional criteria for screening and/testing, if applicable:

16. Describe what the test is designed to measure
17. Describe next steps taken if test detects a condition/problem
18. Describe next steps if no condition/problem detected
19. Describe consequences of detection that would not have caused problems if the screen were not done
20. Include information about chances of true positive result
21. Include information about chances of false positive result
22. Include information about chances of true negative result
23. Include information about chances of false negative result

Does the PDA and/or the accompanying external documentation (including responses to the application for certification) adequately:

- Disclose and describe actual or potential financial or professional conflicts of interest
- Fully describe the efforts used to eliminate bias in the decision aid content and presentation
- Demonstrate developer entities and personnel are free from listed disqualifications in Attachment A
- Demonstrate that the PDA has been developed and updated (if applicable) using high-quality evidence in a systematic and unbiased fashion
- Demonstrate that the developer tested its decision aid with patients and incorporated these learnings into its tool
- Demonstrate that the PDA or supporting document reports readability levels