doi: 10.1111/j.1369-7625.2007.00445.x

Editorial

International Patient Decision Aid Standards (IPDAS): beyond decision aids to usual design of patient education materials

As patient involvement has become part of public dialogue about health care, there has been growing attention to how to support people to behave in ways that allow them to successfully engage in managing their own health and health care. As these behaviours are new to many people, it is important to provide what I will call a 'patient engagement infrastructure'. By that, I mean that patient engagement requires a systematic approach to (1) providing information and skills to interact with providers and the healthcare system and (2) evaluating the epidemiology of the behaviours and skills, and the effectiveness of the infrastructure from both process and outcome perspectives.

A key piece of the patient engagement infrastructure is information necessary to make informed and effective decisions. Considerable research and development consistent with this objective has occurred around patient 'decision aids' (DA), aimed at a limited, but increasing, set of clinical decisions. Decision aids are designed for decisions in which there is no clearly agreed upon best treatment, due to differing side-effect profiles, and different chances of good results.[1] To ensure that patients get the best information for making informed decisions and support for sharing in these decisions, an international collaboration [International Patient Decision Aid Standards (IPDAS) Collaboration] recently reported a set of criteria for judging a good DA.[2] While aimed at improving quality of DAs, I believe the criteria have much broader applicability, and that they represent important research-based principles to guide design of patient education materials.

Evaluating patient education materials

In the IPDAS publication, Elwyn and colleagues reported research and consensus-based standards for recommended content and development processes for DAs to support informed choices about screening and treatment options. The IPDAS criteria presently take the form of the following checklist (Table 1).

The IPDAS criteria are similar to earlier rating efforts, particularly those developed for DISCERN.[3] The IPDAS criteria are a checklist of whether the materials did or did not include a content or process item judged to be important, rather than a quality rating scale. I will argue here that this approach also has broader application to patient education materials.

Are all patient education materials decision aids?

The Cochrane Decision Aid review group's definition identifies a specific subset of patient decisions, mostly surgical, that are 'preference sensitive'. Preference sensitive means that the choice patients should make depends on their own preferences for the outcomes. This prefer-

Table 1 IPDAS patient decision aid user checklist

I. Content: does the patient decision aid…

Provide information about options in sufficient detail for decision making?

- ☐ describe the health condition
- ☐ list the options, including doing nothing
- ☐ describe the natural course without intervention
- ☐ describe procedures
- ☐ describe benefits; harms/side effects of options
- ☐ include chances of positive/negative outcomes

Additional items for tests

- ☐ describe what test is designed to measure
- ☐ include chances of true positive, true negative, false positive, false negative test results
- ☐ describe possible next steps based on test result
- ☐ include chances the disease is found with/without screening
- ☐ describe detection/treatment that would never have caused problems if one was not screened

Present probabilities of outcomes in an unbiased and understandable way?

- ☐ use event rates specifying the population and time period
- ☐ compare outcome probabilities using the same denominator, time period, scale
- ☐ describe uncertainty around probabilities
- ☐ use visual diagrams
- ☐ use multiple methods to view probabilities [words, numbers, diagrams]
- ☐ allows the patient to select a way of viewing probabilities [words, numbers, diagrams]
- ☐ allow patient to view probabilities based on their own situation [e.g. age]
- ☐ place probabilities in context of other events
- ☐ use both positive and negative frames [e.g. showing both survival and death rates]

Include methods for clarifying and expressing patients' values?

- ☐ describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects
- ☐ ask patients to consider which positive and negative features matter most
- ☐ suggest ways for patients to share what matters most with others

Include structured guidance in deliberation and communication?

- ☐ provide steps to make a decision
- ☐ suggest ways to talk about the decision with a health professional
- ☐ include tools [worksheet, question list] to discuss options with others

II. Development process: does the patient decision aid …

Present information in a balanced manner?

- ☐ able to compare positive/negative features of options
- ☐ shows negative/positive features with equal detail [fonts, order, display of statistics]

Have a systematic development process?

- ☐ includes developers' credentials/qualifications
- ☐ finds out what users [patients, practitioners] need to discuss options
- ☐ has peer review by patient/professional experts not involved in development and field testing
- ☐ is field tested with users [patients facing the decision; practitioners presenting options]
- ☐ The field tests with users [patients, practitioners] show the patient decision aid is:
- ☐ acceptable
- ☐ balanced for undecided patients
- ☐ understood by those with limited reading skills

Use up to date scientific evidence that is cited in a reference section or technical document?

- ☐ provides references to evidence used
- ☐ report steps to find, appraise, summarise evidence
- ☐ describe quality of scientific evidence [including lack of evidence]
- ☐ uses evidence from studies of patients similar to those of target audience

Table 1 (Continued)

☐ report date of last update	
☐ report how often patient decision aid is updated	
Disclose conflicts of interest?	
☐ report source of funding to develop and distribute the patient decision aid	☐ report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid
Use plain language?	
☐ is written at a level that can be understood by the majority of patients in the target group	☐ provides ways to help patients understand information other than reading [audio, video, in-person discussion]
☐ is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY]	
Meet additional criteria if the patient decision aid is Internet based	
☐ provide a step-by-step way to move through the web pages	☐ provides security for personal health information entered into the decision aid
☐ allow patients to search for key words	☐ make it easy for patients to return to the decision aid after linking to other web pages
☐ provide feedback on personal health information that is entered into the patient decision aid	☐ permit printing as a single document
Meet additional criteria if stories are used in the patient decision aid	
☐ use stories that represent a range of positive and negative experiences	☐ state in an accessible document that the patient gave informed consent to use their stories
☐ reports if there was a financial or other reason why patients decided to share their story	

ence includes side-effect profiles as well as expected 'good' outcomes. These are the classic 'toss-up' questions. For example, the choice to have a mastectomy or a lumpectomy for breast cancer does not differ substantially in terms of expected mortality, but does differ in terms of whether or not radiation therapy is part of treatment, and whether reconstructive surgery needs to be considered. Not all decisions are toss-ups, or close calls in terms of their consequences. But that does not mean that the IPDAS criteria are not broadly applicable. Many contemporary patient education materials are meant to guide patient involvement in decisions, though the decisions about care continue well beyond the initial intervention. Even for surgical decisions, the treatment may take place at a specific point in time, but the decisions about care go on well beyond the intervention.

A thought experiment may help to test the applicability of the criteria. For example, to stretch considerably beyond a surgical decision in a western country, we could think of the decision for HIV positive mothers in developing countries to breast feed or bottle feed or use mixed methods.[4] Two questions can be asked of each item in the checklist in this situation. (1) Does it apply to the particular topic under consideration? (2) Is the criterion likely to ensure good information? I would argue that only two criteria in the list seem to need adjusting. One is that under 'guidelines for deliberation', it is likely that this needs to address family as well as health care providers. Further, it is quite possible that rather than a worksheet, a dialogue process would be more appropriate. However, the process section of the checklist, which suggests pilot tests, is very likely to identify appropriate corrections. It appears that application of the IPDAS criteria to design of patient education materials in this setting would not require a different design process.

A second thought experiment is to ask, are there existing opportunities where specific guidance of the sort included in the IPDAS standards could markedly improve patient

information and engagement? One such opportunity for important reform would be the application of the IPDAS standards to the universal design of informed consent documents. Presently, the quality of informed consent documents varies widely, and the general guidance supplied by most authorities is very non-specific. If the IPDAS guidelines were implemented as a template, it is highly likely that informed consent documents would begin to become tools that truly support patients making decisions about trial entry and about treatment.

Important pilot tests of the IPDAS checklist have already begun. Coulter and colleagues used a version of the checklist to evaluate a wide variety of patient education materials. They evaluated materials directed at arthritis, chronic obstructive pulmonary disease, measles/mumps/rubella vaccination and healthy eating/obesity. They found that the checklist proved to be a useful tool for assessing the quality of information materials, and that it revealed wide variations in quality. Materials tended to score reasonably well on clarity of structure and layout, having a clear statement of aims and including information on the date of publication. However, they performed significantly worse in relation to the provision of accurate, reliable and sufficiently detailed clinical information to assist patients in decision making. In particular, few materials included a clear presentation of the likely outcomes of treatment, few mentioned clinical controversies or uncertainties, and many failed to acknowledge the patient's decision-making role.[5]

Is the world of patient education materials ready for informed and shared decision making?

A recent report on medication package inserts suggests that patients are beginning to be eager for the type of information suggested in IPDAS. The report, published by the NIHR Health Technology Assessment programme suggests that most patients do not value the written information presently provided and feel it does not meet their needs. Patients report that they need information set in the context of their illness and containing information on both the benefits of the medicine and any side effects. The systematic review on the role and effectiveness of information provided to patients about individual medicines assessed how patients and professionals value package inserts, the role they play in using medicines, and compared the effectiveness of different ways of presenting the information. Results show that while some professionals believe that the primary purpose of written information is to increase patients' compliance, patients use the information to help them decide whether or not to take a medicine in the first place, as well as informing them about ongoing medicine management decisions. The report indicates that the way side effect risk is described has an important impact on the understanding of the likelihood of side-effects and that readability of information, in terms of language and visual presentation, is also very important to patients.[6] While the report contains its own recommendations for reform, I would argue that the IPDAS criteria can contribute to the discussion of how to accomplish patients' objectives.

Revising the general approach to patient information in the direction of DAs is not so radical a proposal as it might appear. In fact, many organizations are moving ahead with this approach, with little fanfare. A recent review of patient education materials for early stage prostate cancer treatment performed in 2001 found that many of the publicly available patient education materials did not contain comprehensive information about both the risks and benefits of each treatment.[7] None explicitly compared outcomes of all treatments in a single summary. In 2007, however, new materials produced by the same provider groups have changed. Materials from the Centers of Disease Control and Prevention (CDC),[8] and from the American Cancer Society (ACS)[9] have been revised to include comprehensive treatment choice information and they encourage patients to share in decision-making. The ACS has DAs for 19 cancers available to the public.

Giving patients what they want?

The partnership between developers of information materials and patients needs to be a shared one. Patients must provide feedback and developers need to actively apply knowledge about how to design materials to enable patients to understand the issues and trade-offs and to select interventions that work for them. Studies looking at whether patients want to engage in shared decision-making have found that they are more likely to say yes after they understand the issues than when asked the question cold, without information. Researchers need to apply the research on decision-making and cognition creatively to explain the consequences of all treatment decisions. Then they need to continue to develop methods for bringing patients and physicians together in a shared decision-making mode. Both parties are moving already to embrace this approach. As the infrastructure improves, so does the likelihood that it will help to restructure the engagement of providers and patients in shared improvement of patient experience with managing health and healthcare.

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References

1 O'Connor AM, Rostom A, Fiset V et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *British Medical Journal*, 1999; **319:** 731–734.
2 Elwyn G, O'Connor A, Stacey D et al. The International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *British Medical Journal*, 2006; **333:** 417.
3 Charnock D, Shepperd S, Needham G, Gann R. DISCERN: an instrument for judging the quality of written consumer health information on treatment choices. *Journal of Epidemiology and Community Health*, 1999; **53:** 105–111.
4 Rollins NC. Infant feeding and HIV. *BMJ*, 2007; **334:** 487–488.
5 Couter A, Ellins J, Swain D et al. *Assessing the Quality of Information to Support People in Making Decisions about their Health and Healthcare*. Oxford: Picker Institute Europe, 2006. http://www.pickereurope.org/Filestore/Downloads/Health-Information-quality-webversion-FINAL.pdf.
6 Raynor DK, Blenkinsopp A, Knapp P et al. A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines. *Health Technology Assessment Journal*, **11.5**. http://www.hta.ac.uk/project.asp?PjtId=1404.
7 Fagerlin A, Rovner DR, Stableford S, Wei JT, Jentoft C, Holmes-Rovner M. Patient education materials about the treatment of early-stage prostate cancer: a critical review. *Annals of Internal Medicine*, 2004; **140**(9)**:** 721–728.
8 Centers for Disease Control and Prevention. *Prostate Cancer*. Centers for Disease Control and Prevention, Department of Health and Human Services, 2006. Available at: http://www.cdc.gov/cancer/prostate, accessed 23 March 2007.
9 NexCura, Inc. *Need Help with Treatment Decisions?* NexCura, 2007. Available at: http://www.cancer.nexcura.com, accessed 23 March 2007.