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# Criteria for Evaluating the Quality of Decision Aids:

# A Critical Appraisal of the IPDAS Presentation of Probabilities Domain

HRM PhD Comprehensive Examination
Independent Study – Final Report

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## Abbreviations

DA – Decision aid

EU– Expected Utility (as in Expected Utility theory)

IPDAS – International Patient Decision Aids Standards

POP – Presentation of probabilities

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## 1. Introduction and Overview

Patient decision aids (DAs) are "tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options."[3] When used, DAs are typically presented to patients by nurses or physicians as part of the medical encounter to facilitate treatment decision making, although some DAs also include patient take – home versions. DAs may come in the form of leaflets, poster boards, videotapes, or computerised media.[1] DAs are of increasing prominence in the medical field: according to Elwyn et al (2006), whereas approximately 15 DAs had been developed in 1999, more than 500 currently exist.[1]

While of increasing prominence, DAs are controversial. As noted by Elwyn et al "debate exists about underlying concepts and about the lack of agreed quality criteria for these tools".[1] In response to this lack of agreement about criteria for evaluating the content, development process and effectiveness of DAs, the International Patient Decision Aids Standards (IPDAS) Collaboration was developed in 2005. This group developed a checklist of "quality criteria" for evaluating the development, content and effectiveness of DAs. Citing a lack of information about the most important factors in improving the quality of treatment decisions, the IPDAS group used a Delphi consensus process to develop the quality criteria. The process included five steps. First, an initial list of 12 broad quality domains was developed based on "quality areas from previous work" and discussion amongst "members of the shared decision making electronic listserve, composed of 181 interested academics and practitioners".[1] The 12 quality domains are shown in Table 1. Second, "background evidence reports" were developed for each quality domain. Third, using these reports 83 quality criteria, each categorized under one of the 12 quality domains, were drafted*. Fourth, members from four participant stakeholder groups (patients, health practitioners, policy makers and DA developers and researchers) were invited to participate in the consensus process. Finally, nominated participants were asked to complete a 2-stage rating process in which they rated "the importance of the quality criteria on a scale from 1=not important to 9=important".[1] Criteria were considered to be important indicators of the quality of the development, content or effectiveness of a given DA (and thus, were included in the final checklist) if they received a weighted median rating of 7 to 9. Of the initial 83 criteria, 74 were retained.

*Elwyn et al (2006) simply state that quality criteria were drafted from the background evidence reports and, therefore, exactly how the quality criteria were drafted is not clear.

| Table 1: Domains Used by the IPDAS Group for Classifying Quality Criteria Included in Their Checklist for Evaluating the Development, Content, and Effectiveness of DAs |
|---|
| ▪ Using a systematic development process<br>▪ Providing information about (treatment) options<br>▪ Presenting probabilities<br>▪ Clarifying and expressing values<br>▪ Using personal stories<br>▪ Guiding/Coaching in deliberation and communication<br>▪ Disclosing conflicts of interest<br>▪ Delivering DAs on the internet<br>▪ Balancing the presentation of options<br>▪ Using plain language<br>▪ Basing information on up-to-date scientific evidence<br>▪ Establishing the effectiveness of DAs |

Voting is one way to determine which criteria should be used to evaluate the development, content and effectiveness of DAs but, from a scientific standpoint, it may not be the best way and there are other more analytic alternatives which could be used. For example, Charles et al (2005) recently developed a set of principles for evaluating the appropriateness of goals or objectives defined for DAs.[2] Charles et al argue first that the goals of DAs should be explicitly stated up front and that criteria used to evaluate DAs should be aligned with the stated goals. Further, they suggest three principles to follow in identifying what constitutes an appropriate goal. First, there should be a clear, explicit rationale for why the goal is important for a DA to address. Second, the constructs underlying any goals should be clearly defined and operationalised so that the impact of specific features of a DA on specified goals (outcomes) can be measured. Third, the mechanism by which the DA is expected to lead to the stated goal (outcome) should be clear: i.e. there should be a strong theoretical basis for making predictions about "the mechanisms by which particular design features of a given DA can be expected to produce a particular outcome."[2]

The principles developed by Charles et al are intended as a general framework that can be applied to evaluate the appropriateness of a variety of goals that have been defined for DAs. This framework can also be used to evaluate the appropriateness of the quality criteria checklist proposed by the IPDAS group, both within the context of a) the goals set for a specific IPDAS quality domain (within which criteria are embedded) and b) the IPDAS-defined overarching goal for DAs. In this paper I show one example of how the Charles et al framework can be applied by undertaking a critical appraisal of the criteria included in one domain from the IPDAS quality criteria checklist: the presentation of probabilities (POP) domain. This approach offers a more systematic and analytic approach to critical appraisal than a simple vote regarding the subjectively experienced importance of each quality criterion to IPDAS-nominated participants.

The POP domain which originally included the thirteen quality criteria shown in Table 2 (note, after the voting process, criteria 3.11 and 3.12 were removed) was selected for this exercise. Two assumptions seem to underlie inclusion of this domain: 1) that communication to patients of the inherent uncertainty in treatment risks and benefits, i.e. the chances that these outcomes will occur and the extent to which they will occur, is important to the treatment decision making process and 2) that communication to the patient of such uncertainties is best achieved through the provision of probability information on the risks and benefits of various treatment options derived from research studies of specified patient groups. At the individual patient level, for a particular treatment, there are 4 possible outcomes: a patient may experience both the benefits and side effects (both to varying degrees of magnitude), the benefits (to varying degrees of magnitude) with no side effects, no benefits but still side effects (to varying degrees of magnitude), or no benefits and no side effects. This raises the question of how to communicate population level probability statistics in a way that makes them meaningful to the individual patient.[2] In addition, the claim by the IPDAS group that presenting probability information to patients is the best way to communicate uncertainty suggested that a more detailed exploration of this domain was warranted.

| **Table 2: Proposed Quality Criteria Describing What and How Probability Information Should be Presented in DAs (i.e. Proposed Criteria for the POP Domain)** | |
|---|---|
| 3.1. | The patient DA presents probabilities using event rates in a defined group of patients for a specified time |
| 3.2. | The patient DA compares the probabilities of options using the same denominator |
| 3.3. | The patient DA compares probabilities of options over the same period of time |
| 3.4. | The patient DA describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') |

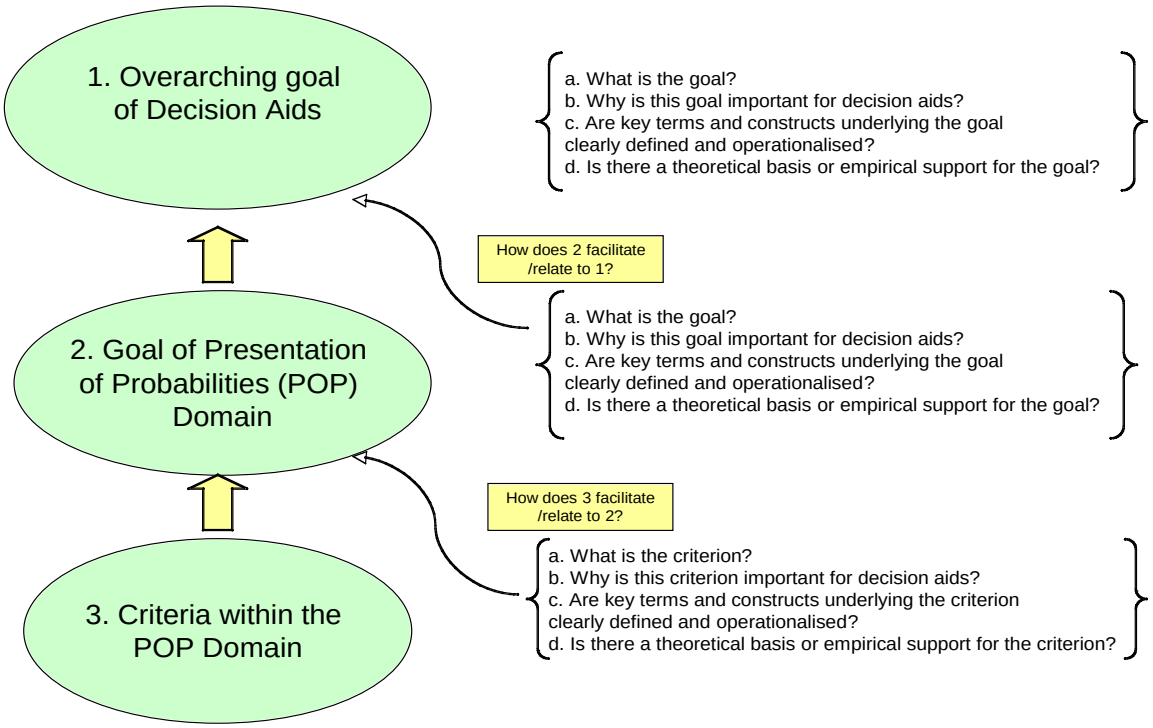
| | |
|---|---|
| 3.5. | The patient DA uses visual diagrams to show the probabilities (e.g. faces, stick figures or bar charts) |
| 3.6. | The patient DA uses the same scales in the diagrams comparing options |
| 3.7. | The patient DA provides more than one way of explaining the probabilities (e.g. words, numbers, diagrams) |
| 3.8. | The patient DA allows patients to select a way of viewing the probabilities (e.g. words, numbers, diagrams) |
| 3.9. | The patient DA allows patients to see the probabilities of what might happen based on their own individual situations (e.g. specific to their age or severity of their disease) |
| 3.10. | The patient DA places the chances of what might happen in the context of other situations (e.g. chances of developing other diseases, dying of other diseases, or dying from any cause) |
| 3.11. | The patient DA has a section that shows how the probabilities were calculated |
| 3.12. | If the chance of disease is provided by sub-groups, the patient DA describes the tool that was used to estimate the risks. |
| 3.13. | The patient DA presents probabilities using both positive and negative frames (e.g. showing both survival rates and death rates) |

## 2. Methods

### *2.1. Adaptation of Charles et al Framework to Critical Appraisal of POP Domain*

The Charles et al framework was adapted to critically appraise the POP domain, and the adapted framework is depicted in Figure 1. By applying the Charles et al framework to the POP domain, three different levels of analysis were identified. The first level represents the identification and evaluation of the overall goals of a DA, as shown in circle 1, Figure 1. Second, the IPDAS group discusses the theme of evaluating the quality of DAs at two different levels of analysis: 1) the 12 broad quality domains (Fig 1, circle 2) and 2) the criteria within each of the 12 quality domains (Fig 1, circle 3). Inclusion of the 12 quality domains implies an assumption on the part of the IPDAS group that they contribute to achieving overall goal of DAs and so it is important to ask what the specific goals are for each domain and how they link to overall goal (Fig 1, circle 2). Inclusion of specific criteria for each domain suggests that, in order for the domain to contribute to the overall goal of DAs, specific requirements must be fulfilled. Therefore, it is also important to ask what the specific requirements (criteria) are for a domain and how they link to the domain goal (Fig 1, circle 3).

**Figure 1: Adapted Charles et al Framework for Critical Appraisal of the IPDAS POP Domain**




The principles suggested by Charles et al for evaluating the goals of DAs can be applied to each circle/level of analysis in the framework and are thus presented beside each circle accordingly. It is important to note that, in relation to circle 1, different authors have proposed different goals for DAs and, therefore, the Charles et al principles could be used to help determine if the first level goal of DAs stated by the IPDAS group is appropriate. However, in this paper I assume that the IPDAS-stated goal for DAs, which is to "improve the quality of decisions (the extent to which patients' decisions are consistent with their informed values)"[1,3], is appropriate and concentrate on applying the Charles et al principles to circles 2 and 3 of the framework. In applying the Charles et al principles to the POP domain (Fig 1, circle 2) I ask the following questions: 1) What is the goal of this domain? 2) Why is this goal important to include in the IPDAS evaluation framework? 3) Are key constructs underlying the goal clearly defined and operationalized so that the relationship between how probabilities are presented in the DA and achievement of specific goals can be measured? and 4) What support is there, either theoretical or empirical, for making predictions about the mechanisms by which particular design features of a given DA can be expected to produce a particular outcome? These same four

questions are addressed in applying the Charles et al principles to the criteria within the POP Domain (Fig 1, circle 3).

### *2.2. Literature Sources*

Material for the critical appraisal of the POP Domain came from several sources including primary materials produced by the IPDAS collaboration such as the IPDAS Collaboration Background Document[4], the IPDAS First-round Voting Document[6], a publication by the IPDAS

group detailing the development of the checklist (Elwyn et al, 2006)[1], and the IPDAS website[5] (see the glossary of terms in Appendix A for descriptions of the IPDAS Background and Voting documents). Secondary references cited within the IPDAS documents were also included. Both the primary and secondary documents were reviewed for statements that would provide evidence that the adapted Charles et al conceptual principles presented in Figure 1 for evaluating the appropriateness of the goal and criteria within the POP domain were met. For example, the IPDAS Background and Voting documents were reviewed for theoretical and empirical support for the IPDAS claim that presenting probability information is the best way to convey information on the risks and benefits of different treatment options to help patients understand the chances that the risks and benefits will occur.

Two documents frequently referenced in this paper are the IPDAS Voting Document and the IPDAS Background Document. The former lists the 13 quality criteria that were originally proposed for the POP domain[6] while the latter was introduced to "supplement the summarized information provided in the IPDAS Collaboration Voting Document".[4] Each section of the Background Document provides a summary of one of the 12 quality domains listed in Table 1 and, according to the IPDAS group, includes "definitions of key concepts; theoretical links between the domain and decision quality; and evidence to support the inclusion or exclusion of suggested domain criteria, including fundamental studies and results from the systematic review of 34 randomised trials".[1] Within the Background Document, discussion of the POP domain is broken down into eight topics: 'presenting numbers', 'visual aids', 'probabilities for tests and screening decisions', 'tailoring probabilities', 'framing probabilities', 'probabilities in context', 'conveying uncertainty', and 'evidence for probabilities used'.

### *2.3. Presentation of Results:*

Upon collection of data from the primary and secondary sources, it soon became apparent that there was a wealth of relevant information to be discussed, and that this material could not all be covered within one paper. Therefore, this paper provides specific examples that, based on the evaluation framework in Figure 1, either support or do not support the inclusion of the POP domain and specific criteria within the domain in the IPDAS quality criteria checklist. More detailed information on the extent to which specific criteria are met is presented in the appendices. Appendix B provides detailed information on the critical appraisal of IPDAS statements regarding the goal of the POP domain (Fig 1, circle 2), Appendix C shows details of the critical appraisal of the criteria within the POP domain (Fig 1, circle 3), and Appendix D outlines a comparison of the POP sections of the IPDAS primary source documents for consistency in statements related to the criteria within the POP domain.

## 3. Results

### *3.1. Critical Appraisal of the Goals of the POP Domain*

#### 3.1.1. Is the Goal of the POP Domain and Rationale for Why it is Important Clearly Stated?

The POP section of the Background Document states that "A key objective of patient DAs is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur."[4] The IPDAS group does not clearly state why this goal is important for DAs to address. Furthermore, the IPDAS group does not provide a justification for why presenting probabilities is the best way achieve this goal.

#### 3.1.2. Are Key Terms and Constructs Defined?

As noted in the adapted Charles et al framework (Figure 1), key constructs underlying the goals of the POP domain need to be clearly defined and operationalised so that the relationship between presenting probabilities and the achievement of specific goals can be measured. The IPDAS group, however, does not clearly define or operationalise the constructs underlying the POP goal. Based on the inferred goal of the POP domain, one might hypothesize that the main construct is patient understanding (of the chances that the benefits and harms associated with treatment choices will occur), but no clarification of this construct is offered. For example, what is meant by 'patient understanding'? How do we define this

construct? and How do we know if 'patient understanding' has been achieved? In addition, other key terms, such as "uncertainty" and "chances" are not clearly defined.

There are other examples within the POP section of the Background Document of key constructs and terms not being defined. Under the 'Tailoring Probabilities' topic, it is suggested that "Whenever possible, individualised risks should be used. Although there is little evidence specifically examining the degree to which individualised risk information facilitates patients' understanding and decisions, it is likely that personally relevant risks will be evaluated more accurately in accord with a patients' values than less relevant risk information."[4] However, the terms "individualized risks", "personally relevant risks" and "relevant risk information" are not defined or operationalised. In addition to the lack of clearly-defined constructs and terms, no measures for key constructs (i.e. patient understanding of the chances that the benefits and harms of a treatment will occur) are offered.

3.1.3. Is there Theoretical or Empirical Support for the Goal of the POP Domain?

A systematic review of DAs published through the Cochrane Collaboration (O'Connor et al, 2003)[7] is offered as empirical support for the premise that presenting probabilities will facilitate achieving the goal of the POP domain. Among other comparisons, the Cochrane review reported on eight studies evaluating the effect of DAs on "patients' perceived probabilities of outcomes". All eight studies showed a trend towards what O'Connor et al describe as more "realistic expectations" in patients who received a DA that included descriptions of outcomes and probabilities. Although the IPDAS group offers this study to support that presenting probabilities may help to achieve the (inferred) goal of helping patients understand the chances related to the benefits and harms of treatment options, the relevance of the studies reported in the Cochrane review for this purpose is questionable. For example, the measurement of what O'Connor et al refer to as "realistic expectations" was, according to O'Connor et al, based on "the percentage of individuals whose judgements corresponded to the scientific evidence about the chances of an outcome for similar people".[7] First, it is unclear what O'Connor et al mean by individuals' "judgements". Second, it is also unclear whether "realistic expectations" is simply capturing the ability of individuals to recall information on probabilities or whether it actually reflects individuals' understanding of a) the research evidence concerning the likelihood of the benefits and harms of various treatment options and b) the relevance of this information to them. Patient recall of probabilities and patient understanding (e.g. interpretation

of what the probabilities mean for them) are two different constructs and, as such, the empirical evidence summarized in the Cochrane review may not offer adequate support that presenting probabilities facilitates patient understanding.

The IPDAS documents do not offer a theoretical basis for making predictions about how presenting probabilities is expected to produce particular outcomes, such as helping patients understand the chances that the possible benefits and harms of their treatment choice will occur. Specifically, no references are cited and no description of a theoretical basis is given.

In summary, the application of Charles et al's principles to section 2 of the adapted framework reveals a number of issues with the POP domain. First, a justification for why the POP goal is important for DAs to address is not provided. Second, no justification is given for why probabilities are the best way to represent uncertainty. Third, neither a theoretical or sufficient empirical basis is offered to facilitate making predictions about the mechanisms by which presenting probabilities can be expected to produce particular outcomes such as helping patients understand the chances that the possible benefits and harms of treatment options will occur. Fourth, key terms, including the constructs underlying the goal of the POP domain, are not clearly defined or operationalised with measures.

#### 3.1.4. Are There any Other Concerns Related to the Goals of the POP Domain?

The same IPDAS references reviewed in Section 3.1.1 were surveyed for additional statements related to the goals of the POP domain (see Appendix B, Table C). For illustrative purposes, selected insights, derived from statements in the POP Section of the Background Document, are described in this section. First, in the introductory paragraph of the Background Document's POP section, it is suggested that "Since no intervention is 100% effective in all patients without harms (including side-effects), probabilities must be presented in decision aids."[4] However, it is also acknowledged that "presenting risk information (probabilities) is problematic because most individuals - including patients and professionals - have difficulty in processing and accurately evaluating probabilities and statistics."[4] and that "individuals would rather use a heuristic such as someone else's evaluation of risks than attend to the figures in order to make a decision."[4] These statements raise a number of questions. For example, why is the IPDAS group recommending the use of probabilities to describe uncertainty while acknowledging that most individuals have trouble understanding this type of information? It is unclear how presenting probabilities will help patients understand the chances that the possible

benefits and harms of their choices will occur if patients and professionals have “difficulty processing and accurately evaluating probabilities” and would prefer not to attend to this type of information.

Second, under the ‘presenting numbers’ topic in the POP section of the Background Document, the authors indicate that "Although many patients prefer to read words rather than numbers, numerical probabilities improve the accuracy of understanding."[4] However, there is no reference to support this statement and it is therefore unclear how or why numerical probabilities improve the accuracy of understanding, particularly if "many patients prefer to read words rather than numbers".[4] The suggestion that presenting probabilities increases the accuracy of understanding also seems to conflict with the notes under the ‘Conveying Uncertainty’ topic in the POP section. For example, the IPDAS group asserts that "It's very important to acknowledge uncertainty in probability estimates. Often the uncertainty is large, especially if evidence is scare or events are rare”[4] and that “Essentially, we never quite know who are the patients who are going to be affected and who the treatment is going to be most useful for ".[4] If the uncertainty in probability estimates always exists and can be quite large, then why does presenting numerical probabilities improve the accuracy of understanding as claimed above? Furthermore, what is meant by the phrase “accuracy of understanding”? Another problem with these statements is they mix two different concepts, the first being an issue of measurement of (i.e. uncertainty in probability estimates from population-level data) and the second being uncertainty regarding what will happen to an individual patient. There is no direct translation of group probabilities about treatment benefits and risks to a given individual patient: even if uncertainty in the probability estimates is reduced or eliminated, we still do not know what will happen to an individual. Therefore, the key question of how to improve patient understanding of uncertainty is not addressed by presenting uncertainty in probability estimates. Thus, in addition to the lack of an explicitly-stated goal, rationale, or constructs and the weak to nonexistent empirical and theoretical support for the goal of the POP domain, there are a number of other statements within the POP section of the Background Document that seem inconsistent with their claim that presenting probability information is the best way to communicate uncertainty about the risks and benefits of treatment options to patients.

## *3.2. Critical appraisal of Criteria within the POP Domain*

### 3.2.1. Are There Clear Statements Explaining the Criteria and Why They Are Important?

The criteria proposed within the POP domain (see Table 2) are clearly stated in the IPDAS Voting Document. In addition, with the exception of the 'Probabilities for Tests and Screening' topic, each of the 8 topics in POP section of the Background Document is supported by an explanation for its importance to the goal of the POP domain. However, a rationale for why each specific criterion within these 8 topics is important to the goal of the POP domain is not offered.

### 3.2.2. Are Key Terms and Constructs Defined for the Criteria Within the POP Domain?

Similar to the findings from section 3.1, key terms and constructs for the criteria within the POP domain are not defined or operationalised. For example, criterion 3.7 indicates that "the patient DA should provide more than one way of explaining the probabilities, including formats such as "words, numbers and diagrams".[6] However it is not clear, for example, whether "using words" refers to general descriptive words or a translation of numerical probability estimates into a scale anchored by phrases and, if so, how this should be done. In addition, measures with which to evaluate each criterion in the POP domain are not provided.

### 3.2.3. Is There Empirical Support for the Criteria Within the POP Domain?

The review of empirical support for the criteria within the POP domain is detailed in Tables D-K of Appendix C, while examples of key findings, grouped by Background Document topic, are provided below.

Presenting Numbers (Tables Di, Dii of Appendix C): Under this topic the IPDAS group suggests that numerical probabilities improve the accuracy of understanding, and that event rates should be used in presenting probabilities. The instructions offered in this section seem to apply to criteria 3.1 – 3.3 (3.1 – 'The patient DA presents probabilities using event rates in a defined group of patients for a specified time', 3.2 - The patient DA compares the probabilities of options using the same denominator', 3.3 – 'The patient DA compares probabilities of options over the same period of time'). Two references are offered for this section, only one of which offers empirical support for the criteria. Specifically, criterion 3.2 seems to be indirectly supported by Woloshin et al (2000)[8], who found that use of "1 in X" scales (i.e. scales with the same numerator but different denominators) are hard for patients to use and "perform

substantially worse than the other scales (evaluated)". The second citation refers to a descriptive paper regarding the development of risk charts and, while related to criterion 3.3, does not offer any empirical support for presenting probabilities of different events over the same period of time.

Visual Aids (Tables Ei, Eii of Appendix C): The Background Document states that visual aids may facilitate accurate understanding of probabilities. This topic maps onto two criteria: 3.5 ('The patient DA uses visual diagrams to show the probabilities (e.g. faces, stick figures or bar charts') and 3.6 ('The patient DA uses the same scales in the diagrams comparing options'. Two references are offered in support of presenting visual aids, but neither offer direct empirical support for the criteria. One of the references cites a study by Feldman-Stewart[9] in which different formats of presenting information visually were compared. While this study offers support for the use of vertical bars, horizontal bars, numbers and systematic ovals over pie charts and random ovals, it does not offer support for the more basic criteria set out by IPDAS in 3.5 and 3.6. Of note, Feldman-Stewart states that "There are few systematic, comprehensive, empirical studies of quantitative information and there is virtually no information about what format is best for patients making medical treatment decisions."[9] Therefore, even the reference provided by the IPDAS group seems to underscore the scarcity of data to support IPDAS recommendations.

Probabilities for Tests and Screening (Tables Fi, Fii of Appendix C): The Background Document devotes a section to the presentation of probabilities for tests and screening. There are a number of instructions provided under this topic. In addition, two references are provided, one of which offers empirical support for the instruction to not use survival times when presenting information for tests and screening. However, this section does not appear to match any criteria listed in the Voting Document. This inconsistency is addressed in section 3.4.

Framing Probabilities (Tables Gi, Gii of Appendix C): Under the framing probabilities topic, the IPDAS group suggests that the way information is presented can affect preferences and decision-making. There are a number of instructions provided, but the only criterion onto which this category maps is 3.13 ('The patient DA presents probabilities using both positive and negative frames'). The only reference offered for framing probabilities (Edwards et al[10]) provides a degree of empirical support for the criterion. However, there are inconsistencies between the criterion and the empirical support. For example, while the Edwards et al[10] study found no clear pattern of effects in positive vs. negative framing, criterion 3.13 states that "the

patient DA presents probabilities using both positive and negative frames". Therefore, even though the cited reference lacks a definitive conclusion on framing event rates, criterion 3.13 provides a clear directive on how this should be done. Although not in full contrast with the evidence, this criterion is also not necessarily in alignment with it either.

Conveying Uncertainty (Tables Ji, Jii of Appendix C): The instructions in this section map onto criterion 3.4 ('The patient DA describes the uncertainty around the probabilities'). However, while the references provided (Edwards et al 2002[11], Skolbekken et al 1998[12]) discuss how and whether to convey uncertainty, they are descriptive in nature and do not offer direct empirical support for why this criterion is important for a DA to address.

Tailoring Probabilities, Probabilities in Context, and Evidence for Probabilities Used (Tables Gi, Hi and Ki of Appendix C): Each of these topics is associated with two or more specific instructions, and maps clearly onto one or more IPDAS criteria. The 'tailoring probabilities' topic maps onto criterion 3.9, the 'probabilities in context' topic maps onto criterion 3.10 and the 'evidence for probabilities used' topic maps onto criteria 3.11 and 3.12 (see Table 2). Despite the mapping of the instructions onto four of the 13 proposed criteria, none of these three categories is supported with specific references in the Background Document.

### 3.2.4. Is There Theoretical Support for the Criteria Within the POP Domain?

The IPDAS authors indicate that, due to a lack of empirical support for communicating probabilities in health, recommendations in the Background Document are "largely made on theoretical grounds, borrowing heavily from work in clinical epidemiology and evidence-based health care, psychology, risk communication and risk perception research, and decision theory".[4] The references cited include Tversky & Kahneman,[13,14] Loewenstein et al,[15] Slovic et al,[16] and von Neumann & Morganstern.[17] Of note, the theories described in these references were all proposed to describe decision-making under uncertainty and thus, contrary to what the IPDAS group suggests, the citations do not borrow from clinical epidemiology or evidence-based health care.

The references offered as theoretical grounds for the IPDAS recommendations do not provide satisfactory support for the POP criteria. First, the theories are not complementary, as each one was developed to replace the previous due to observed violations in predictions made by the predecessor. For example, numerous studies have shown that individuals systematically

violate the predictions of Von Neumann & Morganstern's Expected Utility (EU) model.[13,14] In light of these violations Tversky and Kahneman developed Prospect Theory as an alternative that could explain many observations that EU theory could not. Noting that Prospect Theory was also unable to explain various phenomena related to decision-making under uncertainty, Lowenstein et al and Slovic et al proposed the Risk-As-Feelings hypothesis[15] and the Affect Heuristic,[16] respectively, arguing that affect and emotion, which were ignored in EU theory and Prospect Theory, played an important role in decision-making and explained the inconsistencies between theory and observation for the previous two models. Since the theories above are not complementary, it is unclear how the IPDAS group intended for these to be used as support for the POP criteria. Interestingly, the theories of Lowenstein[15] and Slovic[16] argue that probabilities are not as important to decision-making as cognitive theories suggest, postulating that individuals may be much more "sensitive to the possibility rather than the probability"[15] of events. Thus, the inclusion of these theories as support for the POP domain is even more puzzling since they seem to obviate the importance of presenting probabilities in decision-making. Second, while the references propose different theories for how individuals make decisions under uncertainty, they do not offer an explanation for how the proposed criteria will help achieve the goal of the POP domain of helping patients understand the chances of the benefits and harms of the treatment options occurring or why these criteria are the best ones to use in pursuit of this goal. Therefore, they are irrelevant to the task of providing a theoretical basis to explain the mechanisms by which the POP criteria facilitate the POP goal.

In summary, the application of Charles et al's principles to section 3 of the adapted framework reveals a number of issues related to the criteria within the POP domain. First, although the criteria are clearly stated, the rationale for why each criterion is important for DAs is not provided. Second, the constructs underlying the criteria are not clearly stated and measures for the criteria are not provided. Third, neither a sufficient empirical or theoretical basis is offered to facilitate making predictions about the mechanisms by which the criteria are expected to produce particular outcomes.

### *3.3. Is There Consistency Between IPDAS Documents?*

As noted previously, the two main documents used to support the IPDAS group's quality criteria checklist are the IPDAS Collaborative Background Document[4] and the IPDAS Voting Document[6]. In conducting the critical appraisal of the POP domain a number of inconsistencies

between these documents were noted and as such, the Background and Voting documents were compared for consistency in statements related to the criteria within the POP domain. Details of the comparison are shown in Tables L and M of Appendix D while key findings are described below.

First, for a number of the criteria listed in the Voting Document there is no direct supporting reference provided in the Background Document, regardless of whether the reference was deemed by the present study to provide empirical support (e.g. criteria 3.6, 3.7, 3.11, and 3.13). Second, one criterion, 3.8, is not mentioned at all in the Background Document, leaving one to question the rationale for it's inclusion as a POP criterion in the Voting Document. Third, there are a number of instructions in the Background Document that are not reflected in the Voting Document criteria. For example, the Background Document suggests that "any visual aids should be pilot tested for understanding". However, neither of the two criteria that apply to the visual aid section (3.5 and 3.6) are appropriate options for mapping the pilot testing instruction. Another key discrepancy involves the 'probabilities for tests and screening' topic. This topic is described at length in the Background Document, with up to five different instructions and two references (one of which offers empirical support for the instructions). However, criteria reflecting the instructions in this category are notably absent from the Voting Document. Contrary to the IPDAS assertion that each section of the Background Document provided "evidence to support the inclusion and exclusion of suggested domain criteria", no rationale is provided for this omission, thereby calling into question how and why certain instructions translate into criteria while others do not. Therefore, in summary, a comparison of the IPDAS Background and Voting Documents highlights various discrepancies, ranging from topics in the Background Document not being reflected in the Voting Document criteria to criteria in the Voting Document not being supported with Background Document references.

## 4. Discussion

By applying the principles introduced by Charles et al[2] this paper presents a critical appraisal of the POP domain of the IPDAS quality criteria checklist. Key insights from the critical appraisal are summarised here. First, there is a lack of clarity regarding the goals of the POP domain and why they are important for a DA to address. The IPDAS initiative required participants to vote on which criteria should be included in the quality checklist and therefore, the lack of clarity on why the goal of the POP domain is important for a DA to address calls into

question the basis upon which voters evaluated the importance of proposed criteria within this domain. Second, no justification is offered to explain why the use of probabilities is the best way to convey the uncertainty about the benefits and harms of a treatment choice to an individual in DAs. Third, the constructs underlying the POP domain and criteria are not clearly defined and measures with which to operationalise the constructs are not provided. This is an important limitation because without a clearly-defined construct it is difficult to evaluate whether the literature offered in support of the POP goal is relevant and appropriate. Fourth, based on the inferred construct of patient understanding, the applicability of the empirical support for the POP goal is questionable since it is unproven whether the data suggest that presenting probabilities improves patient recall or patient understanding. In addition, there is a lack of theoretical support to facilitate predictions about the mechanisms by which presenting probabilities will facilitate achievement of the (inferred) goal of the POP domain. Fifth, many terms used in discussing the goal of POP domain, such as “individualized risks” and “personally relevant risks” are not clearly defined.

In addition, although references are offered, the empirical support for the criteria within the POP domain is weak, with only one reference considered to be possibly supportive for one of the 13 criteria.[8] This may not be surprising since, in the POP section of the Background Document, the IPDAS group states that “few (strategies for effectively communicating probabilities in health) have been tested empirically in patient DAs”. However, following this statement the IPDAS group suggests that “recommendations in this document are largely made on theoretical grounds…” but a review of the “theoretical grounds” indicates that the theoretical support is insufficient. This lack of empirical and theoretical support for the criteria within the POP domain raises a number of questions. For example, why have the POP criteria been proposed if they are not backed with strong empirical/theoretical support?, Is there empirical/theoretical support for these criteria, but the reviewers have simply not offered the appropriate references?, and why/how were the references selected for incorporation into the Background Document? Are they the best/most comprehensive references available? What was the logic or search strategy used for the incorporation or exclusion of references?

In addition to the limitations identified through application of Charles et al’s principles, there are a number of other inconsistencies within the IPDAS documents. First, a comparison of the Background and Voting Documents reveals various discrepancies, ranging from topics in the Background Document not being reflected in the Voting Document criteria to criteria in the Voting Document not being supported by the Background Document references. These

discrepancies highlight possible inconsistencies in the IPDAS approach to generating a quality checklist, suggesting that further justification is required for the checklist criteria while also calling into question the validity of the checklist itself.

Inconsistencies can also be found in Elwyn et al[1], an article published in the British Medical Journal that describes the IPDAS group's process for developing the quality criteria checklist. First, Elwyn et al indicate that "Substantive research about the overall effectiveness of patient DAs exists, but little information is available about which components and processes are most influential for improving decision quality."[1] However, if little information is available, then how can the IPDAS group justify the development of 12 quality domains? Moreover, if there is a lack of information, then it seems that the first task for the IPDAS group should be to focus on developing empirical evidence for how best to improve decision quality. Indeed, in the Cochrane Review, O'Connor (one of the leaders of the IPDAS initiative) et al suggest that "qualitative research could provide valuable insight into determining the elements in DA design that are most important."[7] Second, Elwyn et al suggest that "The DA criteria that were most strongly endorsed also had the greatest empirical support."[1] However, this was certainly not the case for the POP domain, where 11 of the 13 proposed criteria were endorsed,[1] despite a clear lack of empirical support. Third, Elwyn et al note that "A second possible weakness is that we asked the participants to rate the criteria against only the "importance" of the criterion for the quality of a DA. Ideally, factors such as measurability and feasibility would have been included".[1] This is indeed a limitation and is exemplified by the lack of proposed measures for the POP criteria or the POP goal. Moreover, if the criteria are not measurable or feasible, then it is unclear how they can be justified as requirements within a quality checklist. Finally, the authors suggest that "The development of future DAs should also be based on theoretical underpinning and on the measurement of appropriate outcomes, in order to determine whether patient DAs accomplish their primary objective - to improve the quality of decisions…"[1] However, precisely because theoretical underpinnings and appropriate outcomes are important components in developing DAs, their omission from the current quality criteria checklist is surprising.

## 5. Conclusion

By applying the principles proposed by Charles et al[2] for evaluating the appropriateness of goals defined for DAs, this paper offers a critical appraisal of the POP domain of the IPDAS

quality criteria checklist. The critical appraisal suggests that there are a number of limitations associated with inclusion of the POP domain in the IPDAS quality criteria checklist.

Therefore, the POP domain (and possibly the checklist overall) may not yet be suitable for use in the evaluating the development process, content and effectiveness of DAs. Instead of moving forward with the current checklist, further work should be done to: a) build a strong empirical and theoretical base upon which quality domains and their respective criteria can be proposed, b) clarify the goals for each proposed quality domain and c) establish clear definitions and measures for underlying constructs and key terms.

## Appendix A: Glossary of Terms

**IPDAS Group –** The IPDAS Collaboration is a group of researchers, practitioners and stakeholders from around the world. The goal of the IPDAS Collaboration is to establish an internationally approved set of criteria to determine the quality of patient decision aids.[5]

**Decision Aids -** Patient decision aids are "tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options."[3] Decision aids may come in the form of leaflets, poster boards, videotapes, or computerised media and, at a minimum, provide information about (treatment) options and their associated outcomes (Elwyn et al, 2006).

**Goal of Decision Aids (as stated by the IPDAS group)** – the objective(s) or outcomes which decision aids are intended to achieve. The goals of decision aids, as defined by the IPDAS group, are: To "improve the quality of decisions (the extent to which patients' decisions are consistent with their informed values"[1,3]

**IPDAS Quality Criteria Checklist** - A checklist (including 12 domains, each with a subset of criteria) developed by the IPDAS group to determine the quality of patient decision aids. In total, there were 83 items in the original checklist. After two rounds of voting by participants nominated by the IPDAS group there was a total of 74 criteria in the checklist.

**POP Domain –** A set of criteria pertaining to what and how probability information on the risks and benefits of treatment options should be presented to patients in decision aids. These criteria are classified by the IPDAS group as belonging to a single theme or domain, the presentation of probabilities (POP) domain, which is one of the 12 domains included in the IPDAS quality criteria checklist

**POP Domain Goal** – While not explicitly stated, the present paper has inferred that the goal of including in the quality criteria checklist (see definition above) the set of criteria relating to the POP domain (specifically, what and how probability information on the risks and benefits of treatment options should be presented to patients in decision aids)

is: to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur.

**POP Criteria** - The POP criteria are a set of 13 criteria proposed by the IPDAS group for inclusion in the POP domain. These criteria can be found in the IPDAS First Round Voting Document (see definition below), and in Table 2 of this paper. The criteria are intended to be used to define both what and how probability information on the risks and benefits of treatment options should be presented to patients in decision aids

**Background Document –** A document developed by the IPDAS group to support the Voting Document. The document includes a section on each of the 12 proposed domains for the quality criteria checklist and was used to inform the identification of the original set of voting criteria. It was available during the voting process for voters interested in learning more about the 12 domains.[5]

**Background Document Topics** - The POP section of the Background Document described the POP domain under 8 different sections, 'presenting numbers', 'visual aids', 'probabilities for tests and screening decisions', 'tailoring probabilities', 'framing probabilities', 'probabilities in context', 'conveying uncertainty', and 'evidence for probabilities used'. Each of these sections is referred to in this report as a "topic".

**Adapted Charles et al Framework** – A framework developed to embody the principles outlined by Charles et al for critically evaluating the goals of a decision aid. The framework is shown in Figure 1 of the present paper.

**Voting Document** - A document developed by the IPDAS group to inform participants of the voting process (to determine which of the proposed criteria should be included in the final quality criteria checklist) on the 12 quality domains and their respective criteria. Voters were asked to rate the importance of each criterion in judging the quality of patient decision aids on a scale of 1-9 (where 1=not important and 9 = very important). This document includes summary statements identifying and describing each of the 12 broad domains and lists the 84 individual quality criteria upon which participants were asked to vote.[5]

**Charles et al's Principles** - Principles outlined by Charles et al[2] for critically evaluating the goals of a decision aid. Charles et al argue that the goals of DAs should be explicitly stated and that the criteria for evaluating DAs need to be aligned with the stated goals. Furthermore, they state that the goals of DAs should be critically evaluated to ensure that they are appropriate, and suggest three principles in identifying what constitutes an appropriate goal. First, there should be a clear, explicit rationale for why the goal is important for a DA to address. Second, the constructs underlying any goals should be clearly defined and operationalised with measures. Third, the mechanism by which the DA is expected to lead to the stated goal should be clear: there should be a strong theoretical basis for a goal, and this theoretical basis should facilitate predictions about "the mechanisms by which particular design features of a given DA can be expected to produce a particular outcome."[2]

# Appendix B: Critical Appraisal of POP Goals

**Table A: Critical Appraisal of IPDAS Statements re: Goals of Decision Aids***

| | |
|---|---|
| **Reference** | 1. Preamble on IPDAS home page (http://ipdas.ohri.ca/) |
| **Goal Stated? (Explicit, Implicit, Not Stated)** | Explicit Goal of IPDAS group:<br><br>"The goal of the IPDAS Collaboration is to establish an internationally approved set of criteria to determine the quality of patient decision aids." |
| **Rationale for why goal is important (for decision-making)** | "There are over 500 patient decision aids available or being developed by many different individuals and groups around the world. However, people have difficulty knowing whether or not a decision aid is a source of reliable health information that can help in decision making." |
| **Theoretical framework for goals identified?** | N/A |
| **Empirical evidence to support goal?** | N/A |
| **Constructs for goal?** | No |
| **Consistency with statement of goals in other IPDAS documents** | N/A |
| **Other Quotes** | |
| **Comments** | |

*Based on a review of all IPDAS documents posted on the IPDAS website plus the IPDAS BMJ article

**Table A (Con'd): Critical Appraisal of IPDAS Statements re: Goals of Decision Aids**

| | |
|---|---|
| **Reference** | 2. IPDAS home page: "What are decision aids?" (http://ipdas.ohri.ca/what.html) |
| **Goal Stated? (Explicit, Implicit, Not Stated)** | Explicit goal of DAs<br><br>"The aim of patient decision aids is to improve the quality of decisions. Decision quality is the extent to which patients choose and/or receive health care interventions that are congruent with their informed and considered values." |
| **Rationale for why goal is important (for decision-making)** | "Complex decisions have multiple options with features that people value differently. Sometimes the scientific evidence about options is limited. Therefore the best choice depends on the personal importance the patient places on the benefits, harms, and scientific uncertainties." |
| **Theoretical framework for goals identified?** | No |
| **Empirical evidence to support goal?** | No |
| **Constructs for goal?** | Patient Values |
| **Consistency with statement of goals in other IPDAS documents** | Matches goal stated in BMJ article |
| **Other Quotes** | Definition of PtDAs: "Patient decision aids are tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options" |
| **Comments** | The definition of best choice (i.e. "the best choice depends on the personal importance…") is not supported by any reference (empirical or theoretical). Also, if this is the definition of a good choice, how can this be used to evaluate/compare decision aids? i.e. how can we evaluate the "quality of decisions"? |

**Table A (Con'd): Critical Appraisal of IPDAS Statements re: Goals of Decision Aids**

| | |
|---|---|
| **Reference** | 3. IPDAS Background document (http://ipdas.ohri.ca/IPDAS_Background.pdf) |
| **Goal Stated? (Explicit, Implicit, Not Stated)** | Explicit goal of DAs (as stated in the POP section, p.11):<br><br>"A key objective of patient decision aids is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur." -<br>Inferred goal of presenting probabilities: to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur." |
| **Rationale for why goal is important (for decision-making)** | "since no intervention is 100% effective in all patients without harms (including side effects), probabilities must be presented in patient decision aids" Notes: This is an inferred rationale. Also, it is not really a rationale for why helping patients understand possible benefits and harms is a good goal. |
| **Theoretical framework for goals identified?** | No theoretical link between domain and decision quality offered. Note, document states that "some strategies for effectively communicating probabilities in health have been proposed, but few have been tested empirically in patient decision aids. Therefore, recommendations in this document are largely made on theoretical grounds, borrowing heavily from work in clinical epidemiology and evidence based health care, psychology (prospect theory - Tversky & Kahneman, 1974, 1981), risk communication and risk perception research (Lowenstein et al, 2001;Slovic et al, 2002), and decision theory (theory of expected utility, Neumann & Morganstern) Note: These appear to be theoretical frameworks supporting the criteria within the POP domain, not theoretical frameworks in support of how/why presenting probabilities facilitates the overall goal of DAs (which, as stated in reference 2 is ..."to improve the quality of decisions...) |
| **Empirical evidence to support goal?** | note: p.15 - empirical evidence for presenting probabilities: Cochrane review (O'Connor et al, 2003) - 7 RCTs that evaluated the effect of patient DAs on patients' perceived probabilities of outcomes: 4 compared a patient decision aid to usual care and 3 compared a simpler to a more detailed patient decision aid. Perceived outcome probabilities were classified according to the percentage of individuals whose judgements corresponded to the scientific evidence about the chances of an outcome for similar patients. All 7 studies showed a trend towards more realistic expectations in patients who received a detailed DA (i.e. included descriptions of outcomes and probabilities) compared to those who did not receive patient DAs with this information included (only 6 had power to detect statistically significant difference). The Cochrane review supports that presenting probabilities helps patients recall possible benefits and harms of choice (but does not necessarily support that the UNDERSTAND the benefits and harms) - What is meant by realistic expectations? |

| | |
|---|---|
| **Constructs for goal?** | Understanding benefits and harms, understanding risk |
| **Consistency with statement of goals in other IPDAS documents** | Not sure the POP goal is consistent with the IPDAS overarching goal of DAs. I.e. does it link into or support the overarching goal? Does not seem to. Does meeting the POP goal facilitate meeting the overarching goal? Not sure yet…. |
| **Other Quotes** | |
| **Comments** | 1. It seems that the theoretical frameworks provided are meant to support the criteria within the POP domain (i.e. rationale for why these criteria are appropriate and why/how they facilitate the goal of presenting probabilities), not theoretical frameworks in support of how/why presenting probabilities facilitates the overall goal of DAs (which, as stated in reference 2 is ..."to improve the quality of decisions...). 2. Also, what is the link between the stated goal and the overall goal of DAs (as stated by IPDAS)? 3. The empirical evidence supports the fact that presenting probabilities in DAs can lead to more realistic expectations but does it offer empirical support for **why** this is an important outcome for DM? |

**Table A (Con'd): Critical Appraisal of IPDAS Statements re: Goals of Decision Aids**

| | |
|---|---|
| **Reference** | 4. IPDAS Voting Document (Feb 1, 2005) (http://ipdas.ohri.ca/IPDAS_First_Round.pdf) |
| **Goal Stated? (Explicit, Implicit, Not Stated)** | Explicit goal of IPDAS: "The IPDAS Collaboration is made up of people from around the world who design, test, compile, provide or use patient decision aids. Their common interest is to reach agreement about how to judge the quality of a patient decision aid"<br><br>Explicit goal of decision aids:"Patient decision aids aim to do three things to prepare a person for decision making: 1. They provide facts about a person's condition, the options, and their features, 2. They help patients to clarify their values (the features that matter most to them), 3. They help patients to share their values with their health care practitioner and others, so a course of action can be planned that matches their values.<br><br>- Inferred goals of presenting probabilities: a) To provide facts about a condition, the options, and their features (as per #1 above) b) to reduce the number/likelihood of poor decisions. (note, inferred from rationale above- i.e. "in theory, decision aids may lead to poor decisions if the probabilities are miscalculated or presented in ways that are misleading") |
| **Rationale for why goal is important (for decision-making)** | "In theory, decision aids may lead to poor decisions if the probabilities are miscalculated or presented in ways that are misleading" **Note:** This supports why the criteria are important when presenting probs, but not really why probabilities are important overall. |
| **Theoretical framework for goals identified?** | No |
| **Empirical evidence to support goal?** | "in the Cochrane collaboration review, 17 of 19 patient decision aids presented probabilities and 3 described the uncertainty associated with the evidence. The methods of displaying probabilities varied. In all 3 studies comparing decision aids with and without probabilities, the number of patients out of 100 reporting probabilities that were realistic, was higher if they used a patient decision aid with probabilities (63-72% correct) than a patient decision aid without probabilities (43-46% correct)." Note: is this really empirical evidence for the goal of presenting probabilities? Review - see reference 3 |
| **Constructs for goal?** | Values clarification, presenting information on options |
| **Consistency with statement of goals in other IPDAS documents** | Aim 1 is consistent (somewhat) with POP - I.e. provide facts about the condition and the patients' options. Aims 2 and 3 are consistent with the overarching goal. |
| **Other Quotes** | 1. "The best (treatment) choice (for a patient) involves matching which features matter most to a person with the option that has these features" 2. "A 'probability' is the chance or likelihood that |

| | |
|---|---|
| | something will happen. It could mean the chance of disease, benefit, harm, or side effect." 3. "It is difficult to know whether or not a decision is a good one" - what is good?<br>4. "The best choice involves matching which features matter most to a person with the option that has those features" (p. 3/27) |
| **Comments** | 1. Goals listed are from the IPDAS voting document intro, not from the POP Domain section. 2. How do people vote on the importance of the criteria, if the goal of the domain is not explicit in the voting document? Is this a problem, or is it ok since they can use the Background document as a reference? |

**Table A (Con'd): Critical Appraisal of IPDAS Statements re: Goals of Decision Aids**

| | |
|---|---|
| **Reference** | 5. Elwyn et al. BMJ 2006 |
| **Goal Stated? (Explicit, Implicit, Not Stated)** | Explicit goal of decision aids: To improve the quality of decisions (the extent to which patients' decisions are consistent with their informed values). P4 |
| **Rationale for why goal is important (for decision-making)** | not provided |
| **Theoretical framework for goals identified?** | No |
| **Empirical evidence to support goal?** | No |
| **Constructs for goal?** | Informed values (?) |
| **Consistency with statement of goals in other IPDAS documents** | Consistent with overarching goal stated on IPDAS home page |
| **Other Quotes** | |
| **Comments** | |

**Table B: Comparison of Goals Stated within IPDAS Background Document**

| Section/Domain | A. Using a systematic development process | B. Providing Information about Options | C. Presenting Probabilities |
|---|---|---|---|
| **Comments in Background Document re: DA Goals** | "Patient decision aids are meant to support informed values-based decision making." (p.3) | "Patient decision aids aim to facilitate informed, values-based decisions about health. This is accomplished by helping each patient determine what is personally important so that they can participate in the decision to the extent that they would like" (p.6) | "A key objective of patient decision aids is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur." (p.11) |
| **Inferred or Explicit Goal of Decision Aids** | To facilitate informed, values-based decision making | To help each patient determine what is personally important in order to facilitate informed, values-based decisions about health. | To provide information to help patients understand risks and benefits of treatment options, and the likelihood that these will occur. |
| **Other quotes** | p. 3. "Practitioners and patients may find it challenging to arrive at a good decision without advance preparation using a patient decision aid that helps patients understand the options and clarify the personal value of their different features." | | |
| **Link to Overarching Goal for Decision aids (as stated on IPDAS home page)** | Matches home page goal, although does not explicitly state which values (i.e. patient values) | Matches overarching goal | Matches objective to make informed decision? |
| **Comments** | 1. Quote from cell C8 seems to infer that the goal of DAs is to help patients understand their options and clarify the personal value of their different features. 2. What is meant by "a good decision"? | | |

**Table B (Cont'd): Comparison of Goals Stated within IPDAS Background Document**

| Section/Domain | D. Clarifying and expressing Values | E. Using personal stories | F: Guiding/Coaching in deliberation and communication |
|---|---|---|---|
| **Comments in Background Document re: DA Goals** | "A key objective of decision aids is to help patients to clarify and communicate the personal value of options, in order to improve the match between what is personally most desirable and which option is actually selected." (p.17) | None explicitly stated | "The objective of a patient decision aid is to help patients make a good decision - one that is well-informed, reflects the patients' values, and is implemented." (p. 28) |
| **Inferred or Explicit Goal of Decision Aids** | To help patients clarify and communicate their personal value for each option in order to improve the match between what patients desire and the therapeutic option they select. | N/A | To help patients make a well-informed decision that reflects their values and that is implemented. |
| **Other quotes** | | "Most patients find stories easier to process and recall than statistics. For example, facts and figures - such as the mean number of times side effects occur and the average intensity or severity of these side effects - are harder for many patients to understand than the stories of patients who have experienced these side effects." (p.24) | |
| **Link to Overarching Goal for Decision aids (as stated on IPDAS home page)** | Matches overarching goal | N/A | Matches overarching goal |
| **Comments** | | | |

**Table B (Cont'd): Comparison of Goals Stated within IPDAS Background Document**

| Section/Domain | G: Disclosing conflicts of interest | H. Delivering decision aids on the internet | I. Balancing the presentation of options | J. Using plain language |
|---|---|---|---|---|
| **Comments in Background Document re: DA Goals** | None explicitly stated | None explicitly stated | "The goal in patient decision making is to enable the patient to make an informed, autonomous decision that reflects their personal preferences. To this end, patient DAs provide patients with information about options and their consequences (benefits/harms) to help them clarify personal preferences." (p. 41) | "Patient decision aids are designed to present medical evidence that assists patients to identify screening, diagnostic testing, and treatment options, to determine their values associated with the potential harms and benefits of these options, and to participate in medical decisions." (p. 45) |
| **Inferred or Explicit Goal of Decision Aids** | N/A | N/A | To provide patients with information about therapeutic options and their benefits and harms so that they can clarify their personal preferences and make an independent decision which is in line with their preferences. | To present evidence on treatment options (including benefits and harms), to help determine patients' values for each option and to help patients to participate in medical decisions. |
| **Other quotes** | | | | |
| **Link to Overarching Goal for Decision aids (as stated on IPDAS home page)** | N/A | N/A | Seems to support POP goal matching DA goal, but what about 'preferences' vs. 'values' - are they the same thing? Can we assume this? | supports values clarification |
| **Comments** | | | | |

**Table B (Cont'd): Comparison of Goals Stated within IPDAS Background Document**

| Section/Domain | K. Basing information on up-to-date scientific evidence | L. Establishing the effectiveness |
|---|---|---|
| **Comments in Background Document re: DA Goals** | None explicitly stated | "There is a reasonable consensus that: a) patient decision aids aim to improve the quality of decision making: and b) quality decisions are those that result in individuals choosing and/or receiving the health care interventions that are most consistent with their informed and considered values (Briss et al, 2004; O'Connor et al, 1997; Stacey et al, 2003; Ratliff et al, 1999; Sepucha et al, 2004). (p. 52) |
| **Inferred or Explicit Goal of Decision Aids** | N/A | To improve the quality of decision making by helping individuals to choose the health care interventions that are most consistent with their informed and considered values. |
| **Other quotes** | | "An assessment of effectiveness of a patient decision aid should, therefore, comprise evaluation of the extent to which it improves the proportion of patients who choose and/or receive health care interventions that are consistent with their individual values." (p. 52) |
| **Link to Overarching Goal for Decision aids (as stated on IPDAS home page)** | N/A | Matches DA goal |
| **Comments** | | It is interesting that there is a section devoted to measuring the effectiveness of decision aids as a whole. This offers some insight into operationalising constructs and measurement. Why is this not offered to each of the different domains and criteria as well? |

**Table C: Summary of Statements Related to POP and Decision Aids Goals From IPDAS Documents**

| IPDAS Quote | Comments |
|---|---|
| **1. Theory/Rationale section of Background Document (POP section, p. 11)** | |
| "A key objective of patient decision aids is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur" | |
| "Since no intervention is 100% effective in all patients without harms (including side-effects), probabilities must be presented in decision aids. However, presenting risk information (probabilities) is problematic because most individuals - including patients and professionals - have difficulty in processing and accurately evaluating probabilities and statistics" | Does this not contradict with the statement in the "presenting numbers' section (p .11) which asserts that "…numerical probabilities improve the accuracy of understanding?"<br><br>Also why is IPDAS recommending that probabilities should be presented if "most individuals - including patients and professionals - have difficulty in processing and accurately evaluating probabilities and statistics"? |
| "The evidence suggests that individuals would rather use a heuristic such as someone else's evaluation of risks than attend to the figures in order to make a decision" | See comment #2 above. i.e. Why is IPDAS recommending the presentation of probabilities if evidence suggests that patients prefer not to attend to figures in order to make treatment decisions? How will presenting probabilities support the overarching goal for decision aids of improving decision quality (the extent to which patients choose options that are congruent with their informed and considered values (as stated by the IPDAS group) if patients having trouble understanding probabilities? |
| "Some strategies for effectively communicating probabilities in health have been proposed (see, for example, Schwartz, 1999), but few have been tested empirically in patient decision aids. Therefore, recommendations in this document are made largely on theoretical grounds, borrowing heavily from work in clinical epidemiology and evidence based health care, psychology (prospect theory, Tversky&Kahneman, 1974;1981), risk communication and risk perception research (Loewenstein et al, 2001;Slovic et al, 2002), and decision theory (theory of expected utility, Neumann & Morganstern) | This highlights that there is little empirical support for how to present probabilities (Also, see section 3 of framework – summary provided in interim report)<br><br>Suggests that the theoretical references are meant to support the criteria (i.e. the HOW to present probabilities, not the WHY). However, based on critical evaluation of the theoretical references, these don't even offer much support for the criteria (see review of theoretical references) |

**Table C (Cont'd): Summary of Statements Related to POP and Decision Aids Goals From IPDAS Documents**

| IPDAS Quote | Comments |
|---|---|
| **Presenting Numbers (From POP section of Background Document p. 11)** | |
| "Although many patients prefer to read words rather than numbers, numerical probabilities improve the accuracy of understanding." ('Presenting numbers' section) | There is no reference to support this statement. Therefore, how do we know that numerical probabilities improve the accuracy of understanding (particularly if "many patients prefer to read words rather than numbers")? Also, does this not conflict with the IPDAS notes on Conveying uncertainty? i.e. if uncertainty around probability estimates is large, then how can presenting probabilities improve the accuracy of understanding? |
| **Conveying Uncertainty (From POP section of Background Document, p. 14)** | |
| "It's very important to acknowledge uncertainty in probability estimates. Often the uncertainty is large, especially if the evidence is scarce or events are rare….Even with the best evidence from large studies, the issue of stochastic uncertainty remains. Essentially, we never quite know who are the patients who are going to be affected and who the treatment is going to be most useful for " ('Conveying Uncertainty' section) | If the uncertainty always exists, and can be quite large, then why does presenting numerical probabilities improve the accuracy of understanding as claimed above? And why are numerical probabilities a better option than communicating risks via words? |
| "Despite these limitations from uncertainty, practitioners generally feel that we can still try to make decisions about what the best treatment plan is for an individual person, based on what happens to these groups of patients in the studies. Hence the value, it is thought, of presenting the information about benefits and harms to aid the decision making process...." ('Conveying Uncertainty' section) | 1. How do we make decisions about individuals based on probabilities for groups of patients? 2. Doesn't this contradict with the suggestion that "whenever possible, individualised risks should be used"? |
| **Tailoring Probabilities (From POP section of background document, p.13)** | |
| "Whenever possible, individualised risks should be used. Although there is little evidence specifically examining the degree to which individualised risk information facilitates patients' understanding and decisions, it is likely that personally relevant risks will be evaluated more accurately in accord with a patients' values than less relevant risk information." | Contradiction with uncertainty in probability estimates?<br>Also, if little evidence, then why do they say "it is likely that personally relevant risks will be evaluated more accurately in accord with a patients' values…"? |

**Table C (Cont'd): Summary of Statements Related to POP and Decision Aids Goals From IPDAS Documents**

| IPDAS Quote | Comments |
|---|---|
| **Comments in IPDAS Voting Document** | |
| p 9. 'How might (presenting probabilities) affect the quality of the decision?" "In theory, decision aids may lead to poor decisions if the probabilities are miscalculated or presented in ways that are misleading." | Is this supposed to be the 'theoretical link' between the domain and decision quality? (if so, it should be stated in background document, as well as here). If does not really offer any such link. Instead, it provides a rationale for how to present probabilities, not for why presenting probabilities can improve decision quality. (i.e. doesn't state that "presenting probabilities will improve decision quality because…") |
| **Comments from IPDAS BMJ Publication** | |
| "Substantive research about the overall effectiveness of patient decision aids exists, but little information is available about which components and processes are most influential for improving decision quality." (p. 2) | If little information is available, then how were the 12 quality domains developed? On what basis were they proposed? If there is little information in this respect, then why are they focusing on a quality checklist - should the focus not be on developing empirical evidence for what works to improve decision quality first? |
| "Twelve panels (a total of 50 international experts) prepared "background evidence reports" for each quality domain. Each report included definitions of key concepts; theoretical links between the domain and decision quality and evidence to support the inclusion or exclusion of suggested domain criteria, including fundamental studies and results from the systematic review of 34 randomised trials" (p2) | The POP section does not actually draw a theoretical link between presenting probabilities and decision quality. It also does not offer a theoretical link between presenting probabilities and the stated goal at the start of the POP section of the background document (i.e. "A key objective of patient decision aids is to provide information to help patients understand the possible benefits and harms of their choice, and the chances that these will occur"). Also, the Cochrane review showed that presenting probabilities in DAs increased the proportion of patients reporting probabilities that were realistic and so may offer support for how presenting probabilities can meet the goal of helping patients understand the possible benefits and harms of their choice, and the chances that these will occur. However, evidence to support the inclusion or exclusion of suggested criteria was weak to nonexistent (thus, the "fundamental studies" to support criteria were lacking). |

**Table C (Cont'd): Summary of Statements Related to POP and Decision Aids Goals From IPDAS Documents**

| | |
|---|---|
| "The decision aid criteria that were most strongly endorsed also had the greatest empirical support." (p. 4) | Is this really the case? 11 of the 13 POP criteria were strongly endorsed, but none of them had empirical support (refer to interim report). |
| "A second possible weakness is that we asked the participants to rate the criteria against only the "importance" of the criterion for the quality of a decision aid. Ideally, factors such as measurability and feasibility would have been included" (p4) | This is an important point in terms of constructs and measurable criteria – i.e. if the criteria are not measurable or feasible, then why/how can they be included as requirements within a quality checklist? |
| "The development of future decision aids should also be based on theoretical underpinning and on the measurement of appropriate outcomes, in order to determine whether patient decision aids accomplish their primary objective - to improve the quality of decisions (the extent to which patients' decisions are consistent with their informed values)" (p 4) | Clear statement about the objective of decision aids. Where does the objective come from? What is it based on? Emp/theoretical support? (i.e. compare against Component 1 of framework).<br><br>Why were "theoretical underpinning" and "measurement of appropriate outcomes" not included as domains if they are deemed important in this paper? |

# APPENDIX C: CRITICAL APPRAISAL OF POP CRITERIA – EMPIRICAL SUPPORT

### Table Di. Presenting Numbers - Overview

| | |
|---|---|
| **Stated Rationale for Criterion:** | Although many patients prefer to read words rather than numbers, numerical probabilities**improve the accuracy of understanding.**<br><br>Event rates are intuitively interpretable because they are natural frequencies with clearly stated reference classes. |
| **Instructions for Criterion:** | 1. Event rates (natural frequencies) are the recommended way to present these probabilities. Event rates for all relevant options and for each relevant outcome should be given, and appropriate time frames and denominators should be provided. RRR, ARR, NNScreen or NNT may help patients compare many options, but they are less likely to be well understood and none of these formats make the baseline risk of disease as explicit as simply presenting event rates for all intervention options being compared.<br><br>2. Constant denominators rather than constant numerators are more readily understood<br>3. For information to be meaningful, it is important to present the timeframe over which events occur, and to use a time frame that patients find useful for health planning and mangement. Although lifetime horizons are often used, 10 year time frames are often more appropriate. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.1 The patient decision aid presents probabilities using event rates in a defined group of patients for a specified time<br><br>3.2 The patient decision aid compares probabilities of options using the same denominator<br><br>3.3 The patient decision aid compares probabilities of options over the same period of time**(note: the instructions do not match this criterion exactly - the criterion discusses using the same frame for all events while the instruction just states that a time frame should be given).** |

## Table Dii: Critical Appraisal of Presenting Numbers References

| | | |
|---|---|---|
| **Reference** | Woloshin et al, MDM 2000;20:298-307. | Woloshin et al, JNCI 2002;94(11):799-804 |
| **Construct** | Presenting Numbers - use constant denominators | Presenting numbers - time frame: although lifetime horizon often used, 10 year time frames are often more appropriate |
| **Study Design** | Study aimed to compare a new VAS scale (the "Magnifier VAS") with three benchmark scales in terms of reliability and validity: linear word scale, "1 in X" scale, linear number scale. Total n= 207, retest for each scale after 2 weeks. | The authors created risk charts that put disease risk in context by placing the 10-year chance of dying from various causes side by side. Charts has age-, sex-, and smoking-specific data about the chance of dying from various causes. |
| **Measures** | For each scale, authors assessed 1. validity (correlation btw participants' direct rankings and scale-derived rankings of the relative probabilities of six events, 2. Test-retest relability - the correlation of responses from test to retest two weeks later and 3) usability (missing/incorrect responses, participant evaluation) | No measures - this is not an actual study. It is a paper describing the development of the risk charts described in cell C15 |
| **Key finding/ Conclusion** | "the 1 in X scale performs poorly and is very difficult for people to useÉ." (see abstract for notes on other scales). The "1 in X" scale had the lowest validity (r=064) and test-retest reliability (r=0.45). Participants described this scale as much harder to use and a poorer indicator of their feelings than the other scales. | No study findings - this is a descriptive paper in which the methods for development of the risk charts are described (and the resulting charts presented) |
| **Does this offer empirical support for the cited POP criterion?** | Yes | No |
| **Why/Why not? (Critical Appraisal)** | Provides empirical support for using consistent denominators instead of consistent numerators. | - this reference did not evaluate how time frames impact patients' understanding of probabilities/chances of event or why 10 year time frame is best. |
| **Comments** | - "the 1 in X scale is commonly used to present the chances of diseases under the assumption that people can use it well." (p.302) However, "despite its widespread use, the 1 in X scale performed substantially worse than all the other scales examined" (p.305)<br>'- "we want to be clear that our study assessed the performance of "1 in X" for eliciting perceptions of chance only - not presenting information. Nonetheless we believe our results should raise questions about the usefulness of this format for presenting data. In fact, a recent study suggests that people have trouble understanding information presented to them in this way" (p.306) | This reference describes the development of risk charts which were based on the 10-year chance of dying from selected causes. The 10-year window was used with the rationale that this "provides a reasonable window into the future". However, evidence for this time frame improving patients' understanding of probabilities is not provided. '- "What is missing from most prevalence or incidence estimates is context....without some context, it is impossible to gauge the magnitude of a disease risk" (p.799) |
| **Action Items** | | See references 11-15. Useful for subsequent work following review of IPDAS references |
| **To which IPDAS Voting document criterion does this item apply?** | 3.2 The patient decision aid compares probabilities of options using the same denominator | Seems at first that this should match 3.3, but technically it does not |

**Table Ei. Visual AIds - Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | Presenting event rates with visual aids such as 100 faces diagrams, bar charts, human figure representations, or flow diagrams may aid accurate understanding of probabilities |
| | By using more than one presentation format, patients are able to choose the format that works best for them. As well, using analogies may be especially useful for preventing small risks (e.g. one person in a football stadium) |
| **Instructions for Criterion:** | Any visual aids used should be pilot tested for understanding,<br><br>Developers should take care to avoid using misleading images (such as graphs with misleading scales) or using different scales within the same patient decision aid.<br><br>There is evidence that the formats which are perceived most accurately and easily by patients are vertical bars, horizontal bars, and systematic ovals. Pie charts and random ovals lead to slower and less accurate estimates. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.5 The patient decision aid uses visual diagrams to show the probabilities (e.g. faces, stick figures or bar charts) |
| | 3.6 The patient decision aid uses the same scales in the diagrams comparing options |

## Table Eii: Critical Appraisal of Visual Aids References

| | | |
|---|---|---|
| **Reference** | Edwards, BMJ 2003;327(7417), p749 | Feldman-Stewart et al, MDM 2000;20:228-238 |
| **Construct** | Visual aids - analogies may be useful | Visual aids - There is evidence that the formats which are perceived most accurately and easily by patients are vertical bars, horizontal bars and sytematic ovals. Pie charts and random ovals lead to slower and less accurate estimates |
| **Study Design** | Not a study - this is an editorial letter | Study was designed to determine which formats for displaying quantities, such as probabilities of treatment risks and benefits are perceived most accurately and easily by patients. Accuracy and speed of processing were compared for six different presentation formats: pie charts, vertical bars, horizontal bars, numbers, systematic ovals, and random ovals. None of the displays included a scale or numeric label (in order to just study the graphic component of the formats). A pilot test was conducted in 36 university students and three subsequent experiments were conducted: test #2 (choice and estimate tasks) in 72 cancer volunteers, test #3 (choice task alone) in 12 cancer volunteers, test #4 (estimate task alone) in 12 cancer volunteers. |
| **Measures** | No Measures - editorial letter | Accuracy (% of errors) and speed of processing (mean response time) |
| **Key finding/ Conclusion** | No study findings - just a discussion of different types of analogies used with patients. | Taken together the results suggest that the formats best for making a choice differ from those best for estimating the size of an amount. For making a choice, vertical bars, horizontal bars, numbers and systematic ovals were equally well perceived; pie charts and random ovals caused slower and less accurate performances. For estimating, numbers led to the most accurate estimates, followed by systematic ovals (the other four formats led to the least accurate estimates). |
| **Does this offer empirical support for the cited POP criterion?** | No | Not necessarily |
| **Why/Why not? (Critical Appraisal)** | Not a study - this is an editorial letter | Study provides empirical support for using vertical bars, horizontal bars, numbers and systematic ovals rather than pie charts or random ovals. Therefore, it supports the instructions in the background section. However, it does not support criterion 3.5 or 3.6 from the IPDAS voting document per se. |
| **Comments** | | "patients with cancer have identified acquiring information not only as important to them, but also as one of their primary unmet needs. Included among the most pressing of their information needs is the requirement for quantitative information such as probabilities of particular events" (p. 288)<br>"Although there are recommendations available on how to display quantitative information, they tend not to be empirically based. There are few systematic, comprehensive, empirical studies of quantitative information and there is virtually no information about what format is best for patients making medical treatment decisions." (p. 229) |
| **Action Items** | | Possibly review refs #19, 36, 37, and 20-24 in subsequent research. |
| **To which IPDAS Voting document criterion does this item apply?** | none | none. The closest criterion would be 3.5 but it is not technically a match since 3.5 simply indicates that a visual aid SUCH AS faces, stick figures or bar charts should be used. The references offers support for exactly which type of visual display should be used. |

**Table Fi. Probabilities for Tests and Screening – Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | None explicitly stated |
| **Instructions for Criterion:** | 1. "The mortality benefit from screening should be presented as the prob a death with and without screening; e.g. the prob of dying of breast cancer in 1000 women who regularly participate in screening and 1000 women who decline screening"<br>2. "It is very important that survival times are NOT used as these are likely to be affected by lead time bias<br>3. Patient DAs should also present the probability of having the target condition detected with and without screening, because many cancer screening programs lead to over-detection of the disease. Disease aids should therefore alert readers to the possibility of screening leading to detection and treatment of disease that might never have caused symptoms had it not been for screening. |
| | 4. Patient DAs about tests or screening programs also need to present information about the chances of receiving a false positive or false negative result. Sensitivity and specificity should be avoided and event rates should be used instead. |
| | 5. Screening may lead to a cascade of events (including follow-up tests and treatments), and the probability of each of these events occurring should also be presented. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | I don't think any of the Voting document criteria reflect this section of the background document. If any, possibly 3.13 - The patient decision aid presents probabilities using both positive and negative frames (e.g. showing both survival and death rates). However, I think criterion 3.13 is more related to the framing of probabilities section of the Background document. |

## Table Fii: Critical Appraisal of Probabilities for Tests and Screening References

| | | |
|---|---|---|
| **Reference** | Barratt et al, 1999 | Welch et al, 2000 |
| **Construct** | Do not use survival times as these are affected by lead time bias | Do not use survival times as these are affected by lead time bias |
| **Study Design** | This is not a study: it is a Users' Guide on how to use guidelines and recommendations about screening | Using population-based statistics from the SEER database, authors calculated the change in 5-year survival from 1950-1955 for the 20 most common solid tumor types. Using tumour as the unit of analysis, chnages in 5-year survival were correlated with changes in mortality and tumour incidence |
| **Measures** | N/A - not a study | Correlation between 5-year survival and mortality and tumour incidence |
| **Key finding/ Conclusion** | N/A - not a study | There was little correlation between the change in 5-year survival for a specific tumour and change in tumour-related mortality (Pearson r = 0.00, Spearman r = -0.07). However, the change in 5-year survival was positively correlated with the change in the tumour incidence rate (Pearson r=+0.49, Spearman r=+0.37). **Conclusion:** changes in 5-year survival over time bear little relationship to changes in cancer mortality. Instead, they appear primarily related to changing patterns of diagnosis |
| **Does this offer empirical support for the cited POP criterion?** | No | Offers support for the construct, but does not correlate with any of the POP criteria |
| **Why/Why not? (Critical Appraisal)** | Not a study | The reference offers support for the fact that survival time does not necessarily correlate with mortality and thus is supportive of the recommendation of not using survival times when communicating the benefit from screening. |
| **Comments** | The reference seems to be more a citation for the statement regarding not using survival time instead of evidence for not using survival time. The citation is referring to the fact that observational studies of screening may be misleading. p.2030..."In these situations (where benefits and harms of treatments are more evenly balanced) observational studies of screening may be misleading. Survival as measured by time of diagnosis may be increased, not because patients live longer, but because screening lengthens the time that they know they have | although the reference supports the IPDAS statements on not using survival time, this criterion is not explicitly stated in the IPDAS voting document/criterion list. To a degree, it fits into 3.13, which indicates that a DA should present probabilities using both positive and negative frames (e.g. showing both survival and death rates). However, it is not an exact match. Why are the screening criteria mentioned in the IPDAS background document but not in the voting document? |
| **Action Items** | | |
| **To which IPDAS Voting document criterion does this item apply?** | none | none |

**Table Gi: Tailoring Probabilities – Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | Although there is little evidence specifically examining the degree to which individualised risk information facilitates patients' understanding and decisions, it is likely that personally relevant risks will be evaluated more accurately in accord with a patients' values than less relevant risk information. |
| **Instructions for Criterion:** | 1. Wherever possible, individualised risks should be used. For example, individualised risk estimates depending on important risk factors such as age, gender, family history, smoking status might be used.<br>2. At a minimum, it should be clear to the user of the patient DA whether the probabilities apply to them based on their gender, age, medcial history, or other risk factors. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.9 the patient DA allows patients to see the probabilities of what might happen based on their own individual situation (e.g. specific to their age or severity of their disease). |

NOTE: The IPDAS Background document does not provide any references for this section

**Table Gii: Framing Probabilities - Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | The way information is presented can affect preferences and decision-making. Thus, patient DA developers should be aware of potential framing effects |
| **Instructions for Criterion:** | 1. Framing effects are minimised if visual aids such as 100-faces diagrams are used, because they show the number of patients experiencing the outcome and the # patients not experiencing the outcome. Simply giving the % of pts who experience an event does not achieve this as clearly....<br><br>2. Event rates presenting both positive and negative frames can be used, but may lead to information overload. An alternative is for writers to acknowledge explicitly the frame used and encourage patients to reformat the information for themselves.<br><br>3. Formats such as RRR, ARR and NNT can be misleading, because they do not make explicit the baseline risk of the target condition |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.13 - The patient aid presents probabilities using both positive and negative frames (possibly?) |

**Table Hi: Critical Appraisal of Framing Probabilities References**

| | |
|---|---|
| **Reference** | Edwards et al, 2001 |
| **Construct** | The way information is framed can affect preferences and decision making |
| **Study Design** | Systematic literature review on communication of risks in one-to-one health care encounters. Studies in 9 different manipulation categories were collected. |
| **Measures** | Methods score was applied to each study. Effect sizes calculated where possible, but there were too few papers in most categories (except for gain vs. loss framing) to conduct a meta-analysis. Therefore results are presented as a summary of th studies in each category, followed by a 'synthesis' of the principal findings an issues. |
| **Key finding/ Conclusion** | Only four manipulation categories had three or more studies (positive vs. negative framing, gain vs. loss framing, absolute risk/NNT vs. relative risk information, and more data points vs. fewer. **Findings:** No clear pattern of effects in negative vs. positive framing. Loss framing is more effective in influencing screening uptake behaviours than gain framing (OR 1.18, 95%CI 1.01-1.38). There is a pattern of evidence suggesting that providing more information, which is more understandable to the patient, is associated with improved patient knowledge and a greater wariness to take treatments or participate in trials Relative risk reduction information regarding treatments or tests appears to be much more "persuasive" than the |
| **Does this offer empirical support for the cited POP criterion?** | Unclear |
| **Why/Why not? (Critical Appraisal)** | This paper offers support for the contention that the way information is framed can affect preferences and decision-making. I addition it offers empirical support for loss framing and presentation of RRRs being more influential than gain framing and ARRs, respectively. It also suggests that provision of more information may lead to better patient decision-making (although this suggestion is based on a collection of studies in different manipulation categories). However, the only IPDAS statement in the 'Framing Probabilities' section of the Background document (p. 13) that seems to match up with these findings is the suggestion that the way probs are framed can influence decision making. The statements that "RRR, ARR and NNT can be misleading...." does not quite match the Edwards reference, since the latter simply suggests that RRR is more persuasive than ARR/NNT. Also, the IPDAS statements regarding positive vs. negative framing does not quite match the Edwards **findings,** although Edwards et al (p. 76) do suggest in their discussion that "...it may be advisable for both positive and negative formats to be presented in usual practice if clinicians wish to avoid the risk of manipulating patient choices even by s |
| **Notes** | There are other references that would apply to this criterion category (i.e. see 'conveying uncertainty' refs) |
| **Comments** | |
| **To which IPDAS Voting document criterion does this item apply?** | 3.13 (?) |

**Table Hii: Probabilities in Context – Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | Disease-specific probabilities (or the benefits of various disease-specific interventions) are hard to understand in isolation. Therefore, patient Das need to help patients put disease (or intervention-) specific information into context. |
| **Instructions for Criterion:** | 1. Patient DAs need to help patients put disease (or intervention-) specific information into context.<br><br>2. One way is to provide estimates of the 10-year chance of developing or dying from various diseases (or dying from any causes) for men/women, smokers/non-smokers at various ages. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.10 - The patient DA places the chances of what might happen in the context of other situations (e.g. chances of developing other diseases, dying of other diseases, or dying from any cause). |

NOTE: The IPDAS Background document does not provide any references for this section

**Table Ji: Conveying Uncertainty – Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | Even with the best of evidence from large studies, the issue of stochastic uncertainty remains. Essentially, we never quite know who are the patients who are going to be affected and who the treatment is going to be the most useful for. Often uncertainty is large, especially if the evidence is scarce or events are rare. |
| **Instructions for Criterion:** | 1. It's very important to acknowledge uncertainty in probability estimates<br>2. It's probably wise to do simple things like rounding off numbers (to avoid false illusions of precision), using phrases like "our best guess is", give ranges, or provide 95% confidence intervals<br><br>3. One way to deal with uncertainty might be to say "If 100 patients like you are given no treatment for 5 years, 92 will live and 8 will die. I do not know whether you will be one of the 92 or of the 8. Then, if 100 patients like you take a certain drug every day for five years, 95 will live and five will die. Again I do not know whether you are one of the 95 or one of the 5"<br>4. Despite the limitations from uncertainty, practitioners generally feel that we can still try to make decisions about what the best treatment plan is for an individual person, based on what happens to these groups of patients in the studies. Hence the value, it is thought, of presenting information about benefits and harms to aid the decision making process. Both sources of uncertainty should be acknowledged in comprehensive discussions of risks in patient decision aids. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.4 The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') |

## Table Jii: Critical Appraisal of Conveying Uncertainty References

| **Reference** | Edwards et al, BMJ 2002;324:827-830. | Skolbekken et al, 1998 |
|---|---|---|
| **Construct** | not sureÉreference follows quote "even with the best evidence from large studies, the issue of stochastic uncertainty remains" | One way to deal with uncertainty might be to say "If 100 patients like you are given no treatment for 5 years, 92 will live and 8 will die. I do not know whether you will be one of the 92 or of the 8. Then, if 100 patients like you take a certain drug every day for five years, 95 will live and five will die. Again I do not know whether you are one of the 95 or one of the 5" |
| **Study Design** | Not a study. This article is a non-systematic review. Authors reviewed literature addressing shared decision-making for communicating risks, supporting patients' decisions, and the specific issue of risk communication about cancer. | Not a study. This article discusses issue with communicating clinical benefits (i.e. communicating risk reduction achieved by cholesterol reducing drugs) |
| **Measures** | N/A - not a study | N/A - not a study |
| **Key finding/ Conclusion** | No study findings | No study findings |
| **Does this offer empirical support for the cited POP criterion?** | no | No |
| **Why/Why not? (Critical Appraisal)** | No study findings | No study findings |
| **Notes** | On p. 829, authors state that "It may be helpful to discuss the frequencies of outcomes but still leave room to explore uncertainties that persist" and "Most of the data available also entail uncertainties. Honesty about this may enhance the role of and respect for professionals, not diminish them" | On page 1957-8, authors state the following: "One way of informing patients has been suggested by Hanne HollnagelÉHer strategy is based on the principles of acknowledging that there is uncertainty involved, avoiding value-laden words such as "risk" or "chance", using absolute estimates, and avoiding relative estimates. For a patient fitting the 4S study criteria, her message would then be "if 100 people like you are given no treatment for five years 92 will live and 8 will die. I do not know whether you will be one of the 92 or of the 8. Then, if 100 patients like you take a certain drug every day for five years, 95 will live and five will die. Again I do not know whether you are one of the 95 or one of the 5" |
| **Comments** | This reference addresses not only conveying uncertainty but other issues in presenting information such as framing effects, references points etc. However, it is only cited under the 'conveying uncertainty' heading | The articles referenced in this section of the IPDAS background document seem to offer neither empirical nor theoretical support for conveying uncertainty. They are just papers that discuss how/whether to convey uncertainty (and the discussions are not based on evidence or theory). Similar to the reference above, this article addresses other issues in communicating clinical benefits on top of conveying uncertainty, but is only cited on the 'conveying uncertainty' heading. |
| **To which IPDAS Voting document criterion does this item apply?** | 3.4 - The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') | 3.4 - The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') |

**Table Ki: Evidence for Probabilities Used – Overview**

| | |
|---|---|
| **Stated Rationale for Criterion:** | To enhance transparency and allow patients and practitioners to see for themselves where the probabilities come from, a technical appendix or something similar should be provided. |
| **Instructions for Criterion:** | 1. To enhance transparency and allow patients and practitioners to see for themselves where the probabilities come from, a technical appendix or something similar should be provided.<br><br>2. The appendix can outline data sources, populations from which probs are obtained and an calculations or modeling that was done to derive the probs in the DA.<br><br>3. Developers may want to include a decision analyst or other experienced modeler on their team to help obtain useful probability estimates<br><br>4. If decision analysis is used to structure the DA, then the probabilities used should be presented in accordance with 1,2. |
| **To Which Criteria in the Voting Document do the instructions/points apply?** | 3.11 - the way the probabilities were calculated is described (in a reference section or accessible technical document) |
| | 3. 12 - If the chance of disease is provided by sub-groups, the tool that was used to estimate these risks is described (in a reference section or accessible technical document) |

NOTE: The IPDAS Background document does not provide any references for this section

# Appendix D: Comparison of POP Sections of IPDAS Background and Voting Documents

### Table L: Comparison of POP Criteria Listed in the IPDAS Voting Document with the IPDAS Background Document

| Voting Document Criterion (p.10 of first round voting doc) | | Discussed in Background Document? | If yes, which section? | Reference provided in Background Document? (No, Yes directly in text, yes if considering references at end of section) | If Provided, does reference offer empirical support for criterion? | Comments |
|---|---|---|---|---|---|---|
| 3.1 | The patient decision aid presents probabilities using event rates in a defined group of patients for a specified time | Yes | Presenting Numbers | Yes, indirectly if using reference section (Gigerenzer G BMJ 2003;327:741-4., Schwartz et al. JNCI Monographs, 1999;25:124-33.) | No | Although references do not offer empirical or theoretical support, statements within the papers support criterion 3.1 |
| 3.2 | The patient decision aid compares the probabilities of options using the same denominator | Yes | Presenting Numbers | Yes, directly in text | Yes | References offers empirical support for the problems with using the same numerator. Therefore, it indirectly offers support for using the same denominator when describing event rates instead |
| 3.3 | The patient decision aid compares probabilities of options over the same period of time | Somewhat | Presenting Numbers | Yes, directly in text | No | The reference and the discussion in the background document relate to the importance of providing a time frame when describing event rates. However, neither states that the same time frame should be used for all options. Therefore, the reference and discussion in Background match somewhat to this criterion, but not exactly. Also, the reference provided does not offer empirical support for time frames: it just discusses the importance of including them. |
| 3.4 | The patient decision aids describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') | Yes | Conveying Uncertainty | Yes, directly in text AND indirectly if using reference section (Schwartz et al 1999) | No, see comments | The articles referenced in this section of the IPDAS background document seem to offer neither empirical nor theoretical support for conveying uncertainty. They are just papers that discuss how/whether to convey uncertainty (and the discussions are not based on evidence or theory). Although Schwartz et al does not offer empirical or theoretical support, statements within the paper support criterion 3.4 |
| 3.5 | The patient decision aid uses visual diagrams to show the probabilities (e.g. faces, stick figures or bar charts) | Yes | Visual Aids | Yes, directly in text AND indirectly if using reference section (Gigerenzer 2003) | No, see comments | The reference (Feldman-Stewart et al) offers empirical support for using vertical bars, horizontal bars, numbers and systematic ovals rather than pie charts or random ovals. However, it does not offer empirical support showing that using visual aids helps patients understand probabilities or for why visual aids are needed. Although Schwartz et al does not offer empirical or theoretical support, statements within the paper support criterion 3.5 |
| 3.6 | The patient decision aid uses the same scales in the diagrams comparing options | Yes | Visual Aids | No | N/A | |

## Table L (continued): Comparison of POP Criteria Listed in the IPDAS Voting Document with the IPDAS Background Document

| Voting Document Criterion (p.10 of first round voting doc) | | Discussed in Background Document? | If yes, which section? | Reference provided in Background Document? (No, Yes directly in text, yes if considering references at end of section) | If Provided, does reference offer empirical support for criterion? | Comments |
|---|---|---|---|---|---|---|
| 3.7 | The patient decision aid provides more than one way of explaining the probabilities (e.g. words, numbers, diagrams) | Yes | Visual Aids | No | N/A | The instruction does not seem explicit enough in the background document - ie Background doc states that "by using more than one presentation format, patients are able to choose the format that works best for them". This matches criterion 3.7 but the instruction is so mildly worded that it does not come across as being an absolute IPDAS requirement |
| 3.8 | The patient decision aid allows patients to select a way of viewing the probabilities (e.g. words, numbers, diagrams) | No | N/A | N/A | N/A | |
| 3.9 | The patient decision aid allows patients to see the probabilities of what might happen based on their own individual situations (e.g. specific to their age or severity of their disease) | Yes | Tailoring Probabilities | Yes, indirectly if using reference section (Schwartz 2003) | No | Although Schwartz et al does not offer empirical or theoretical support, statements within the paper support criterion 3.9 |
| 3.10 | The patient decision aid places the chances of what might happen in the context of other situations (e.g. chances of developing other diseases, dying of other diseases, or dying from any cause) | Yes | Probabilities in Context | Yes, indirectly if using reference section (Schwartz 2003) | No | Although Schwartz et al does not offer empirical or theoretical support, statements within the paper support criterion 3.10 |
| 3.11 | The patient decision aid has a section that shows how the probabilities were calculated | Yes | Evidence for Probabilities Used | No | N/A | Is empirical support really needed for this sort of criterion? |
| 3.12 | if the chance of disease is provided by sub-groups, the patient decision aid describes the tool that was used to estimate the risks. | Yes | Evidence for Probabilities Used | No | N/A | Is empirical support really needed for this sort of criterion? |
| 3.13 | The patient decision aid presents probabilities using both positive and negative frames (e.g. showing both survival rates and death rates) | Yes, but unclear (see comments) | Framing Probabilities | Yes directly in text AND indirectly is using reference section (Schwartz 2003) | Unclear/No | 1. There is an instruction in the framing probabilities section to this criterion. However, it states that providing both positive and negative frames may lead to information overload. Therefore, the instruction is not entirely consistent with the supporting reference (which finds no difference/preference for positive vs.negative framing) or the IPDAS criterion. |

## Table M: Comparison of Instructions in the IPDAS Background Document and Criteria Listed in Voting Document

| Background Document Section | Instruction | Is there an IPDAS Voting Document Criterion which matches this instruction? | Which IPDAS Criterion? | Comments |
|---|---|---|---|---|
| Presenting Numbers | 1. Event rates (natural frequencies) are the recommended way to present these probabilities. Event rates for all relevant options and for each relevant outcome should be given, and appropriate time frames and denominators should be provided. | Yes | 3.1 The patient decision aid presents probabilities using event rates in a defined group of patients for a specified time | |
| Presenting Numbers | 2. Constant denominators rather than constant numerators are more readily understood | Yes | 3.2 The patient decision aid compares the probabilities of options using the same denominator | |
| Presenting Numbers | 3. For information to be meaningful, it is important to present the timeframe over which events occur, and to use a time frame that patients find useful for health planning and mangement. Although lifetime horizons are often used, 10 year time frames are often more appropriate. | Yes | 3.3 The patient decision aid compares probabilities of options over the same period of time | |
| Visual Aids | Presenting event rates with visual aids such as 100 faces diagrams, bar charts, human figure representations, or flow diagrams may aids accurate understanding of probabilities | Yes | 3.5 - The patient DA uses visual diagrams to show the probabilities | |
| Visual Aids | By using more than one presentation format, patients are able to choose the format that works best for them. | Yes | 3.7 - the patient DA provides more than one way of explaining the probabilities | |
| Visual Aids | Analogies may be especially useful for presenting small risks (e.g. one person in a football stadium crowd) | No | N/A | This seems to be more of a suggestion than an actual instruction, so the lack of a voting document criterion may not be an issue. |
| Visual Aids | Any visual aids used should be pilot tested for understanding, | No | N/A | |
| Visual Aids | Developers should take care to avoid using misleading images (such as graphs with misleading scales) or using different scales within the same patient decision aid. | Yes | 3.6 The patient decision aid uses the same scales in the diagrams comparing options | |

## Table M(continued): Comparison of Instructions in the IPDAS Background Document and Criteria Listed in Voting Document

| Background Document Section | Instruction | Is there an IPDAS Voting Document Criterion which matches this instruction? | Which IPDAS Criterion? | Comments |
|---|---|---|---|---|
| Visual Aids | There is evidence that the formats which are perceived most accurately and easily by patients are vertical bars, horizontal bars, and systematic ovals. Pie charts and random ovals lead to slower and less accurate estimates. | No | N/A | This statement is not directly reflected in criterion 3.5, which simply states that "The patient decision aid uses visual diagrams to show the probabilities (e.g. faces, stick figures or bar charts)" |
| Probabilities for Tests and Screening | 1. "The mortality benefit from screening should be presented as the prob a death with and without screening; e.g. the prob of dying of breast cancer in 1000 women who regularly participate in screening and 1000 women who decline screening" | No | N/A | see cell C9 in 'Probs for Tests and Scrn - EMP' worksheet |
| Probabilities for Tests and Screening | 2. "It is very important that survival times are NOT used as these are likely to be affected by lead time bias | No | N/A | see cell C9 in 'Probs for Tests and Scrn - EMP' worksheet |
| Probabilities for Tests and Screening | 3. Patient DAs should also present the probability of having the target condition detected with and without screening, because many cancer screening programs lead to over-detection of the disease. Disease aids should therefore alert readers to the possibility of screening leading to detection and treatment of disease that might never have caused symptoms had it not been for screening. | No | N/A | see cell C9 in 'Probs for Tests and Scrn - EMP' worksheet |
| Probabilities for Tests and Screening | 4. Patient DAs about tests or screening programs also need to present information about the chances of receiving a false positive or false negative result. Sensitivity and specificity should be avoided. | No | N/A | see cell C9 in 'Probs for Tests and Scrn - EMP' worksheet |
| Probabilities for Tests and Screening | 5. Screening may lead to a cascade of events (including follow-up tests and treatments), and the probability of each of these events occurring should also be presented. | No | N/A | see cell C9 in 'Probs for Tests and Scrn - EMP' worksheet |

## Table M (continued): Comparison of Instructions in the IPDAS Background Document and Criteria Listed in Voting Document

| Background Document Section | Instruction | Is there an IPDAS Voting Document Criterion which matches this instruction? | Which IPDAS Criterion? | Comments |
|---|---|---|---|---|
| Tailoring probabilities | 1. Wherever possible, individualised risks should be used. For example, individualised risk estimates depending on important risk factors such as age, gender, family history, smoking status might be used. | Yes | 3.9 the patient DA allows patients to see the probabilities of what might happen based on their own individual situation (e.g. specific to their age or severity of their disease). | |
| Tailoring probabilities | 2. At a minimum, it should be clear to the user of the patient DA whether the probabilities apply to them based on their gender, age, medical history, or other risk factors. | Yes | 3.9 the patient DA allows patients to see the probabilities of what might happen based on their own individual situation (e.g. specific to their age or severity of their disease). | |
| Framing Probabilities | 1. Framing effects are minimised if visual aids such as 100-faces diagrams are used, because they show the number of patients experiencing the outcome and the # patients not experiencing the outcome. Simply giving the % of pts who experience an event does not achieve this as clearly.... | No | N/A | |
| Framing Probabilities | 2. Event rates presenting both positive and negative frames can be used, but may lead to information overload. An alternative is for writers to acknowledge explicitly the frame used and encourage patients to reformat the information for themselves. | Somewhat | 3.13 - The patient aid presents probabilities using both positive and negative frames (??) | Somewhat' because the instruction suggests that positive and negative frames may lead to information overload while the criterion states that both positive and negative frames should be used. Nonetheless, this seems to be the appropriate criterion for the instruction |
| Framing Probabilities | 3. Formats such as RRR, ARR and NNT can be misleading, because they do not make explicit the baseline risk of the target condition | No | N/A | Does this statement indirectly match criterion 3.1 because it is against RRR, ARR etc and thus one can assume that event rates are preferred. (??) |
| Probabilities in Context | Patient Das need to help patients put disease (or intervention-) specific information into context | Yes | 3.10 - The patient DA places the chances of what might happen in the context of other situations (e.g. chances of developing other diseases, dying of other diseases, or dying from any cause). | |
| Probabilities in Context | 1. One way is to provide estimates of the 10-year chance of developing or dying from various diseases (or dying from any causes) for men/women, smokers/non-smokers at various ages. | Yes | 3.10 - The patient DA places the chances of what might happen in the context of other situations (e.g. chances of developing other diseases, dying of other diseases, or dying from any cause). | |

## Table M (Continued): Comparison of Instructions in the IPDAS Background Document and Criteria

| Background Document Section | Instruction | Is there an IPDAS Voting Document Criterion which matches this instruction? | Which IPDAS Criterion? | Comments |
|---|---|---|---|---|
| Conveying Uncertainty | 1. It's very important to acknowledge uncertainty in probability estimates | Yes | 3.4 The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') | |
| Conveying Uncertainty | 2. It's probably wise to do simple things like rounding off numbers (to avoid false illusions of precision), using phrases like "our best guess is", give ranges, or provide 95% confidence intervals | Yes | 3.4 The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') | |
| Conveying Uncertainty | 3. One way to deal with uncertainty might be to say "If 100 patients like you are given no treatment for 5 years, 92 will live and 8 will die. I do not know whether you will be one of the 92 or of the 8. Then, if 100 patients like you take a certain drug every day for five years, 95 will live and five will die. Again I do not know whether you are one of the 95 or one of the 5" | Somewhat | Possibly 3.4 | This instruction applies to criterion 3.4 The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is'). However, this way of presenting the uncertainty is not explicitly stated in the criterion |
| Conveying Uncertainty | 4. Despite the limitations from uncertainty, practitioners generally feel that we can still try to make decisions about what the best treatment plan is for an individual person, based on what happens to these groups of patients in the studies. Hence the value, it is thought, of presenting information about benefits and harms to aid the decision making process. **Both sources of uncertainty should be acknowledged in comprehensive discussions of risks in patient decision aids.** | Yes | 3.4 The patient decision aid describes the uncertainty around the probabilities (e.g. by giving a range or by using phrases such as 'our best guess is') | This instruction is more specific than the criterion (3.4) itself. However, it does apply to this criterion |
| Evidence for probabilities used | 1. To enhance transparency and allow patients and practitioners to see for themselves where the probabilities come from, a technical appendix or something similar should be provided. | Yes | 3.11 - the way the probabilities were calculated is described (in a reference section or accessible technical document) | |
| Evidence for probabilities used | 2. The appendix can outline data sources, populations from which probs are obtained and any calculations or modeling that was done to derive the probs in the DA. | Yes | 3.11 - the way the probabilities were calculated is described (in a reference section or accessible technical document). 3.12 - If the chance of disease is provided by subgroups, the patient DA describes the tool that was used to estimate the risks. | |
| Evidence for probabilities used | 3. Developers may want to include a decision analyst or other experienced modeler on their team to help obtain useful probability estimates | No | N/A | This seems to be more of a suggestion than an actual instruction, so the lack of a voting document criterion may not be an issue. |
| Evidence for probabilities used | 4. If decision analysis is used to structure the DA, then the probabilities used should be presented in accordance with 1,2. | Yes | 3.11 - the way the probabilities were calculated is described (in a reference section or accessible technical document), possibly 3.12 as well. | |

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