

Developing a quality criteria framework for patient decision aids: online international Delphi consensus process

Glyn Elwyn, Annette O'Connor, Dawn Stacey, Robert Volk, Adrian Edwards, Angela Coulter, on behalf of the International Patient Decision Aids Standards (IPDAS) Collaboration

Abstract

Objective To develop a set of quality criteria for patient decision support technologies (decision aids).

Design and setting Two stage web based Delphi process using online rating process to enable international collaboration.

Participants Individuals from four stakeholder groups (researchers, practitioners, patients, policy makers) representing 14 countries reviewed evidence summaries and rated the importance of 80 criteria in 12 quality domains on a 1 to 9 scale. Second round participants received feedback from the first round and repeated their assessment of the 80 criteria plus three new ones.

Main outcome measure Aggregate ratings for each criterion calculated using medians weighted to compensate for different numbers in stakeholder groups; criteria rated between 7 and 9 were retained.

Results 212 nominated people were invited to participate. Of those invited, 122 participated in the first round (77 researchers, 21 patients, 10 practitioners, 14 policy makers); 104/122 (85%) participated in the second round. 74 of 83 criteria were retained in the following domains: systematic development process (9/9 criteria); providing information about options (13/13); presenting probabilities (11/13); clarifying and expressing values (3/3); using patient stories (2/5); guiding/coaching (3/5); disclosing conflicts of interest (5/5); providing internet access (6/6); balanced presentation of options (3/3); using plain language (4/6); basing information on up to date evidence (7/7); and establishing effectiveness (8/8).

Conclusions Criteria were given the highest ratings where evidence existed, and these were retained. Gaps in research were highlighted. Developers, users, and purchasers of patient decision aids now have a checklist for appraising quality. An instrument for measuring quality of decision aids is being developed.

Introduction

Trials indicate that decision aids are superior to standard counselling in improving patients' knowledge and realistic expectations about the results of treatments and other procedures.¹⁻⁴ Outcomes such as perceived involvement, agreement between values and choice, and decisional conflict have changed in a desirable positive direction.¹ Decision aids can also affect the uptake of options, reducing the use of some procedures^{5,6} and increasing the use of others.¹ These effects are desirable when decision aids are unbiased and the motivation is to rectify variations in practice due to poor comprehension or disregarding of

patients' preferences. Concerns will emerge if decision aids affect uptake rates because of bias or inaccuracy.

More than 500 decision aids now exist, and many are available on the internet.⁷ However, their quality varies. Debate exists about underlying concepts⁸ and about the lack of agreed quality criteria for these tools. The International Patient Decision Aids Standards (IPDAS) Collaboration adapted an approach used for appraising clinical guidelines (AGREE collaboration)⁹ and established an international collaboration of different stakeholder groups. The aim was to achieve an international consensus based framework of quality criteria for patient decision aids that would act as a checklist for developers and users.

Methods

Evidence about the overall effectiveness of patient decision aids exists,¹ but little information is available about which components and processes are most influential for improving "decision quality."¹⁰ We established a consensus based Delphi process integrating empirical evidence and the views of experts and stakeholders.

Delphi consensus technique and study management

Defining quality domains—Delegates at the 2nd International Shared Decision Making conference (Swansea, 2003) identified an initial list of quality areas¹ and expanded it into 12 broad quality domains (see extra table on bmj.com). We used these 12 broad quality domains to specify which background evidence reports were needed.

Developing background evidence reports—Twelve panels (a total of 50 international experts) prepared "background evidence reports" for each quality domain.¹¹ From these reports (available online¹¹), we drafted quality criteria.

Producing quality criteria—We subjected the quality criteria to iterative consultation and editing by a steering group, a methods group, evidence review panels,¹¹ and finally by a plain language expert. We established a final set of 80 quality criteria.

Establishing participant stakeholder groups—We considered four stakeholder groups to be relevant: patients, health practitioners, policy makers, and decision aid developers and researchers. Participants were nominated by the IPDAS Collaboration, by the

Department of General Practice, Centre for Health Sciences Research, Cardiff University, Cardiff CF14 4YS

Glyn Elwyn
research professor,
primary medical care

Adrian Edwards
research professor,
primary medical care

University of Ottawa and Ottawa Health Research Institute, Clinical Epidemiology Program, Ottawa, ON, Canada K1Y 4E9

Annette O'Connor
professor

School of Nursing, University of Ottawa, Ottawa, ON, Canada K1H 8M5

Dawn Stacey
assistant professor

Department of Family and Community Medicine, Baylor College of Medicine, Houston, TX 77098-3915, USA

Robert Volk
associate professor

Picker Institute Europe, King's Mead House, Oxford OX1 1RX
Angela Coulter
chief executive

Correspondence to:
Glyn Elwyn
elwyng@cardiff.ac.uk

BMJ 2006;333:417-9



An extra table, a statistical appendix, and a checklist are on bmj.com



This is the abridged version of an article that was posted on bmj.com on 14 August 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38926.629329.AE>

Cochrane Collaboration Consumers Group, and by word of mouth. Inclusion criteria were familiarity or awareness of patient decision aids

Rating quality criteria—We invited nominated participants by email to complete a two stage online rating process.¹¹ For each quality domain, we asked participants to read the background reports and rate the importance of quality criteria on a scale from 1 = not important to 9 = very important. At the second round, we presented raters with a summary of the results for each domain and the first round ratings for each of the criteria.

Analysis of ratings

After the first round, we calculated aggregate ratings and summarised comments. We obtained a weighted median by calculating a separate empirical cumulative distribution function for each stakeholder group. We calculated the median of this distribution (equimedian). We based thresholds for retaining quality criteria in the framework on the overall equimedian and the level of disagreement among participants at the second round. We considered that participants “disagreed” if 30% or more of the ratings were in the lower third (ratings 1-3) and 30% or more of the ratings were in the upper third (ratings 7-9). We regarded quality criteria with an overall equimedian rating of 7 to 9 (without disagreement) as “important” and included them.

Results

We included the following quality domains in the final quality criterion framework: (1) systematic development process; (2) providing information about options; (3) presenting probabilities; (4) clarifying and expressing values; (5) using patient stories; (6) guiding or coaching in deliberation and communication; (7) disclosing conflicts of interest; (8) delivering patient decision aids on the internet; (9) balancing the presentation of options; (10) using plain language; (11) basing information on up to date scientific evidence; and (12) establishing effectiveness.

We invited 212 people to the Delphi process (125 researchers/researcher practitioners, 44 patients, 25 policy makers, and 18 health professionals). Of those invited, 122 provided ratings at the first round; 104/122 (85%) participants completed both rating rounds (table). Participants were from 14 countries, although most were from the United States (65), Canada (50), the United Kingdom (44), and Australia (18).

Free text comments prompted the addition of three new criteria for the second round. The extra table on bmj.com reports the equimedian ratings achieved

for each criterion after the second round. Of the 83 criteria, 41 were given an overall equimedian rating of 9, 28 a rating of 8, and 7 a rating of 7. None of the criteria had evidence of disagreement.

For 16 criteria, evidence existed of significant differences between stakeholder groups’ ratings. Compared with other stakeholder groups, researchers generally gave lower ratings to criteria. Exclusion of any one set of stakeholder results did not change the overall inclusion or exclusion of criteria.

Discussion

Principal findings

This Delphi process has provided substantial consensus about a framework of quality criteria for patient decision aids. The decision aid criteria that were most strongly endorsed also had the greatest empirical support. Where stakeholder groups’ ratings differed, the researcher group tended to give lower ratings. The use of “patient stories” in decision aids caused considerable discussion. Concerns exist because patient stories have the potential to introduce significant bias and depend on how the stories are selected and presented.¹² Given that decision making is strongly influenced by self identification with “similar others,” this area needs further investigation. The values clarification technique of describing the physical, emotional, and social effects of options to help patients to explore “experienced utility” was strongly endorsed.¹³

The endorsed criteria are available as a checklist (see bmj.com). This checklist enables the users of existing decision aids to assess the content, development process, and effectiveness of patient decision aids they encounter. The quality criteria in the checklist form an important resource for the developers of new decision aids and could guide researchers to create a validated quality assessment scale that could generate quantitative scores.

Weaknesses and strengths

A potential weakness of the study is the extent to which the participants were not independent of the research agenda. Some raters might have considered patient decision aids to offer more advantages than disadvantages. However, consistency was high across groups and where differences appeared researchers generally gave lower ratings than the other stakeholders. 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.¹⁴ A strength of the study is the appropriate use of a Delphi consensus process.¹⁵ We took care to ensure the availability of existing empirical evidence,¹¹ the use of plain language, and that equal weighting was given to stakeholder groups’ ratings.

Results in context

This study represents the first international effort to build on the work of the Cochrane Collaboration’s systematic review group and establish a normative consensus on quality criteria for patient decision aids.¹ We recognise that the checklist contains a substantial number of criteria and might be considered to represent an “ideal” construction that may be difficult

Participants’ characteristics and responses by stakeholder group and country

	No of participants invited	Round 1		Round 2	
		No	Response rate (%)	No	Response rate (%)
Stakeholders					
Patients	44	21	48	19	91
Practitioners	18	10	56	9	90
Policy makers	25	14	56	9	64
Researchers	125	77	62	67	87
Total	212	122	58	104	85

What is already known on this topic

Decision support technologies for patients (also known as decision aids) have received increasing interest over the past decade

A systematic review of randomised controlled trials confirmed many positive outcomes when these tools are used by patients and healthcare providers

No agreement exists about the content of the active components of decision aids, and no guidance exists about quality standards for their development and evaluation

What this study adds

A Delphi process, supported by summarised evidence reports, has provided substantial consensus about a framework of quality criteria for patient decision aids

The criteria are available as a users' checklist and are being used as a guide to developers of decision support

to attain. However, this quality framework emphasises the need to strive for designs that have favourable effects on decision quality. The criteria are not meant to be prescriptive, and an unresolved debate remains about what constitutes a minimum set of domains and criteria that should be met by a patient decision aid.

Implications

Quality criteria for patient decision aids are relevant to patients, healthcare professionals, healthcare service purchasers, and policy makers. The IPDAS Collaboration checklist is designed for existing users and for developers of new decision aids. To take the field forward, two things are now needed: firstly, to use the IPDAS framework as a basis for developing a validated instrument for assessing the internal quality of the decision tool; secondly, to develop an agreed way to

measure the impact of such tools on a range of outcomes.

We thank the following for their assistance: P Shekelle (USA), J Muir Gray (UK), P Tugwell (Canada), J Wennberg (USA), and the other participants in the consensus process. We acknowledge Raymond Ramirez and J Scott Smith for development and management of the Delphi process website.

Contributors: See bmj.com.

Funding: Canadian Institutes of Health Research Group grant; Cardiff University internal funding.

Competing interests: AO'C receives financial support from the not for profit Foundation for Informed Medical Decision Making, Boston. This foundation receives royalties from Health Dialog, a commercial producer and promoter of patient decision aids. Other authors: none declared.

- O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Rovner D, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2003;(1):CD001431.
- Molenaar S, Sprangers MA, Postma-Schuit FC, Rutgers EJ, Noorlander J, Hendricks J, et al. Feasibility and effects of decision aids. *Med Decis Making* 2000;20:112-27.
- Estabrooks C, Goel V, Thiel E, Pinfold P, Sawka C, Williams I. Decision aids: are they worth it? A systematic review. *J Health Serv Res Policy* 2001;6:170-82.
- Entwistle V. The potential contribution of decision aids to screening programmes. *Health Expect* 2001;4:109-15.
- Whelan T, Levine M, Willan A, Gafni A, Sanders K, Mirsky D, et al. Effect of a decision aid on knowledge and treatment decision making for breast cancer surgery: a randomized trial. *JAMA* 2004;292:435-41.
- Kennedy AD, Sculpher MJ, Coulter A, Dwyer N, Rees M, Abrams KR, et al. Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs. *JAMA* 2002;288:2701-8.
- Evans R, Elwyn G, Edwards A. Making interactive decision support for patients a reality. *Inform Prim Care* 2004;12:109-13.
- Charles C, Gafni A, Whelan T, O'Brien MA. Treatment decision aids: conceptual issues and future directions. *Health Expect* 2005;8:114-25.
- Cluzeau FA, Burgers JS, Brouwers M, Grol R, Mäkelä M, Littlejohns P, et al. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care* 2003;12:18-23.
- Sepucha KR, Fowler EJ, Mulley AG. Policy support for patient-centered care: the need for measurable improvements in decision quality. *Health Aff (Millwood)* 2004;suppl web exclusive:VAR54-62.
- International Patient Decision Aid Standards (IPDAS) Collaboration. Background evidence reports from expert panels for 12 quality domains. <http://ipdas.ohri.ca/> (accessed Jan 2006).
- Ubel PA, Loewenstein G. The role of decision analysis in informed consent: choosing between intuition and systematicity. *Soc Sci Med* 1997;44:647-56.
- Kahnemann D. Experienced utility and objective happiness: a moment-based approach. In: Kahnemann D, Tversky A, eds. *Choices, values and frames*. New York: Cambridge University Press and Russell Sage Foundation, 2000:673-92.
- Brook RH. Appropriateness: the next frontier. *BMJ* 1994;308:217-8.
- Campbell SM, Cantrill JA, Roberts D. Prescribing indicators for UK general practice: Delphi consultation study. *BMJ* 2000;321:425-8.

(Accepted 13 July 2006)

doi 10.1136/bmj.38926.629329.AE

And we thought the British were obsessed with the weather

As a British doctor living and working in Germany, I remain constantly amazed by the frequency and ease—or perhaps what is better described as insatiable compulsion—with which the German people, including the younger generation, visit their local general practitioner. (It is also troubling to note the effect the German language has on the length of the average sentence, even when writing in English.) I was therefore not surprised to learn that one of the country's leading newspapers has a whole section of the weather report dedicated purely to "Biowetter"—in other words, how the weather today may affect you and your health.

During a spell of unceasing rain and snow, the Biowetter report stated: "People suffering from rheumatological diseases and arthritis must prepare themselves for a worsening of their pain. Cardiovascular patients with a tendency to high blood pressure

should not do anything strenuous. With the current weather conditions, those susceptible are likely to suffer from headaches. Operation scars are likely to be more noticeable."

This led me to wonder whether a daily, medically focused, weather report fortifies the beliefs and encourages the consultation-seeking behaviour of the health-preoccupied German population? Or is it there at the request of overworked, underpaid GPs to try to curtail the never ending presentation of minor ailments? Who knows? But perhaps, on my return to Britain, I might start a beautiful new career as a medical weather forecaster.

Jane E Graham *visiting doctor, Heidelberg University Hospital, Heidelberg, Germany* (jegraham@doctors.org.uk)