

Development of a standardized face and content validity test to evaluate patient questionnaires for clinical practice

Virginie Bagneux MA², Nicola Barnes MA¹,
Benoit Arnould MSc, MA¹

¹ Mapi Values, Lyon, France

² Université de Savoie, Chambéry, France

Introduction

Patient questionnaires are a well-documented means of contributing to the healthcare process. Alongside the shift to patient-centered care, there has been much speculation about the potential of these instruments for use in clinical practice. The International Society for Quality of Life Research (ISOQOL) recently organized a meeting specifically on Patient-Reported Outcomes in clinical practiceⁱ, attesting to the interest currently being shown for this subject in the international arena.

However, although a number of patient questionnaires now purport to have been developed and validated specifically in and for the clinical practice setting, the uptake of these tools into the routine care setting has been slow. Reasons for this, and possible solutions, have been discussed in a number of articles^{1,2,3}. The reluctance to use these tools in clinical practice has been disappointing, given the potential advantages^{3,4} of integrating these tools into the clinical care setting, including:

- initiating conversations about treatment or disease issues⁵
- supporting diagnosis and shared-decision-making⁶
- evaluating quality of care⁴
- improving patient benefit⁴

Why is it that the well-developed instruments available are not being used? Could it be because “good” instruments are not so good for clinical practice?

Indeed, the criteria used to evaluate patient questionnaires^{7,8} were developed for research^{9,10} and not for clinical practice. Yet the criteria for judging instruments are not the same in these contexts^{11,12}. The need to understand what clinicians expect from tools for clinical practice led to the presented project. The premise was that these tools would be more likely to be used if their pertinence to physicians were ensured during their development.

The PRAGmatic Content and face validity Test (PRAC-Test) was therefore designed, following classic methodology on questionnaire development, with the aim of better understanding how doctors evaluate

patient questionnaires for use in clinical practice, covering all criteria leading to their adaptation or rejection. The challenge of this project was to develop a standard assessment that could be used during development of patient questionnaires for decision-making and for screening. The work was presented at ISOQOL in Budapest, and the IVth Congress of Health Psychology in the French Language, both in June 2007.

This manuscript describes the development process for the PRAC-Test, the methodology used, the content of the test, and discusses possible applications.

Methods

Literature Review

A literature review was carried out with the aim of identifying the criteria used to judge questionnaires for clinical practice. The databases consulted were the Mapi Research Trust's internal database, and Medline. Selection criteria required the article to be in English, published after 1996 (or previously known to us), with a direct link to the aim of the review and dealing with patient questionnaires from the user's point of view. The attributes identified were used as a basis for clinician interviews.

Exploratory Interviews

■ CLINICIAN RECRUITMENT

Six specialists and five General Practitioners (GPs) whose main activity was their medical practice, (hospital or private practice), and with prior knowledge of patient questionnaires were recruited. The specialists were one cardiologist, one allergist, one neuro-geriatrician, one respirologist, one urologist and one ophthalmologist.

■ CLINICIAN INTERVIEWS

Interviews aimed at capturing the criteria relevant to these health professionals when judging patient questionnaires for use in clinical practice. A specific interview guide was developed and followed. The first part comprised open questions pertaining to clinicians' attitudes towards these tools and their experience thereof. The aim was to capture spontaneous reactions and so identify a priori representations. The

KEYWORDS

PATIENT QUESTIONNAIRES, CLINICAL PRACTICE, QUESTIONNAIRE DEVELOPMENT, FACE VALIDITY, CONTENT VALIDITY

second part was semi-directive. Each questionnaire element was focused on, (e.g. instructions, response choices, score) and the clinicians' evaluation criteria were discussed. The aim was to obtain specific elements and examples. The third part of the interview was based on patient questionnaires provided to the clinicians, and captured their reactions to these measures.

Special attention was given to allowing space for free expression regarding attitudes to patient questionnaires. All interviews were transcribed, either from tapes or from notes taken during the interviews, and analyzed.

Item Generation

First, a list of attributes was generated using data from the literature review and clinician interviews. Attributes were defined as categories of properties or characteristics necessitating independent dimensions during evaluation. The first version of the “PRAGmatic Content and face validity Test” (PRAC-Test) was created.

Content validity testing

A semi-directive interview guide was developed, covering all elements of the PRAC-Test. Two GPs and two specialists were recruited, different to those for the exploratory interviews, but using the same inclusion and exclusion criteria. The specialists were one psychiatrist and one otorhinolaryngologist. In addition, the pilot version of the PRAC-Test was sent to clinicians who had participated in the exploratory interviews, for comments.

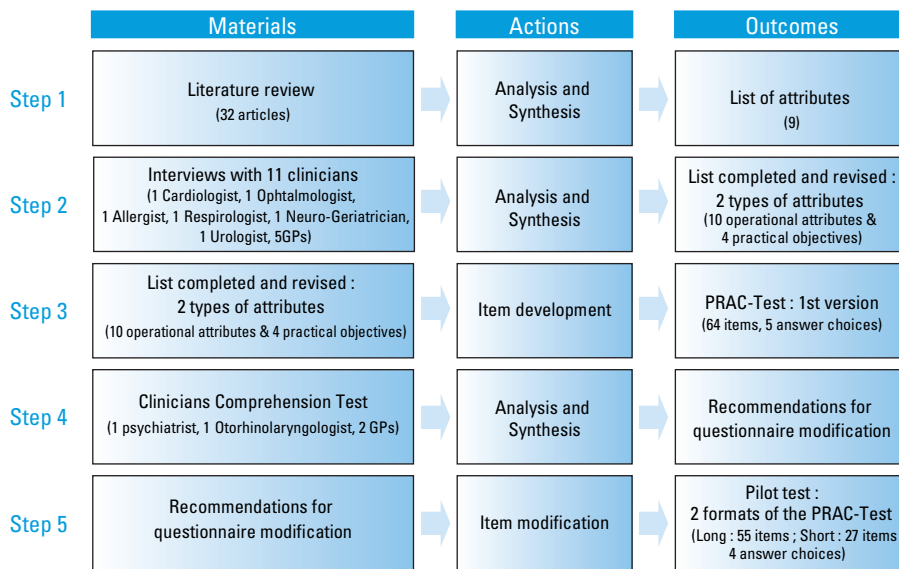
Participating clinicians were presented with two tools for clinical practice (a Visual Analog Scale for pain and the HIT-10 for the evaluation of headaches¹³). During the comprehension tests, clinicians were asked about their past experience with patient questionnaires, and about their general impressions thereof. Clinicians were given the PRAC-Test and asked questions about all of its aspects in order to 1) evaluate their understanding of the PRAC-Test 2) evaluate its relevance and applicability 3) identify any ambiguities or unclear formulations 4) obtain suggestions for reformulation or additions.

All comments made (verbal and non-verbal) were noted during the interviews.

ⁱ ISOQOL conference on Patient-Reported Outcomes in Clinical Practice; Budapest; June 24-26 2007

Figure 1.

Overview of PRAC-Test Development Process



Item generation

The attributes and objectives identified were used to develop a pilot version of the PRAC-Test, containing 64 items. Response choices were either open-responses or Likert-type scales.

Content Validity Interviews

The pilot version of the PRAC-Test was comprehension tested during face-to-face interviews with four clinicians at their place of work. Of the participating clinicians, two were GPs and two were specialists. One was female. The interviews lasted between 25 and 45 minutes. For the clinicians to whom the pilot questionnaires were sent for comment, replies were received for 4 of the 6 specialists, and 3 of the 5 GPs.

Overall, comments regarding the PRAC-Test were positive, such as "simple", "concise", "precise and well formulated". The most frequent criticism concerned excess length or redundancy of questions. As a result of these confirmatory interviews, most items were reduced in length, and nine were deleted. Some items were reformulated, and response choices were altered to multiple-choice as the alternation between open and Likert-type responses was considered bothersome.

Finalized Version of the PRAC-Test

In view of the desired applications of the PRAC-Test, two versions of the test were created: long (55 items) and short (27 items). The long version is designed for use in pilot-tests during questionnaire development so that health-care professionals can contribute to the development process. The first section captures information on aims, limits and use of the questionnaire, and representations of patient questionnaires. There follows a detailed evaluation of the questionnaire, with 4 Likert-type response options from "No, not at all" to "Yes, absolutely", and space for free expression in each section, to be used for questionnaire modification. The short version is identical, without these open questions. This version is for use in a validation study, to obtain clinicians' opinions about the questionnaire developed. It contains only multiple choice or Likert-type response options.

Discussion

The need for patient questionnaires that are designed for clinical practice is consistent with new health-system approaches³³. Numerous articles refer to psychometric properties, and some evaluate existing tools or refer to their attributes^{2,21}. However, no work that we are aware of specifically explores the needs of clinicians in terms of patient questionnaires. Indeed, the reasons for

Results

Literature Review

In total, 136 articles were identified. Following review, 32 articles were retained for analysis. The criteria identified for judging patient questionnaires were grouped into the following attributes:

Table 1.

Attributes identified and their references.

Attribute Identified	Reference
Acceptability	Morris, 1998 ¹ ; Beznak, 1998 ¹⁴ ; Lohr, 1992 ¹⁵ ; Wilson & Cleary, 1995 ¹⁶ ; Peterson, 2001 ¹⁷ ; Evans & Crawford, 1999 ¹⁸
Practicality	Nelson & Berwick, 1989 ² ; Detmar, 2002 ³ ; Wilson & Cleary 1995 ¹⁶ ; De Dombal, 1978 ¹⁹ ; Duffy, 2005 ²⁰ ; Greenfield & Nelson, 1992 ²¹ ; Wright, 2003 ²²
Ease/Simplicity	Arnould, 2006 ¹¹ ; Wilson & Cleary 1995 ¹⁶ ; McHorney & Tarlov, 1995 ²³ ; Willke, 2004 ²⁴
Comprehension/Clarity	CDER, 2006 ⁷ ; Ragab, 2003 ²⁵ ; Evans, 2004 ²⁶ ; Marquis, 2004 ²⁷ ; Paul, 1999 ²⁸ ; Jagsch & Pils, 2006 ²⁹
Pertinence	Dennison, 2002 ⁴ ; CMPH, 2005 ⁵ ; Chassany, 2002 ¹⁰ ; Zou, 2004 ³⁰
Usefulness	Wright, 2003 ²² ; Meers & Singer, 1996 ³¹
Confidence based on scientific criteria	Dennison, 2002 ⁴ ; Peterson, 2001 ¹⁷
Transparency	De Dombal, 1978 ¹⁹
Attractiveness	Streiner & Norman, 1989 ³²

Exploratory Interviews

Six telephone interviews were carried out with two GPs and four specialists, and five face-to-face interviews with three GPs and two specialists at the clinicians' place of work. Two clinicians were female. The interviews lasted 45 minutes on average. During the interviews, the attributes identified in the literature were confirmed and identified as "operational attributes". *Attractiveness* was changed to *Design/*

Attractiveness to reflect the vocabulary used by the clinicians. *Pertinence* was expanded and renamed *Structure and Flow*. The interviews also captured a new set of attributes that define objectives to be met by patient questionnaires for them to be considered useful by clinicians. The following four objectives were identified: *Justify/Inform-Document*, *Standardize*, *Communicate*, *Decide*.

clinicians' reluctance to use patient questionnaires, and issues surrounding this reluctance, are central to the debate about the use of these tools in clinical practice. A recent application of the theories on diffusion of innovation³⁴ identify three "clusters of influence", namely "the perceptions of the innovation, the characteristics of the individuals who may adopt the change, and contextual and managerial factors within the organization". All of these one can link directly to clinicians, although especially notable here are the "perceptions of innovation", captured within the PRAC-Test; direct communication with these professionals is essential in order to shed light on key issues. Beyond practical features such as length, usefulness (or lack thereof) seems to be more determinant of clinicians' choice of tool. The practical objectives of questionnaires identified in the exploratory interviews show that the tool must be useful to the clinician; to justify/document, standardize, communicate or decide. This is captured in the "practical objectives" section of the PRAC-Test. Moreover, the tool evaluated has to allow easy, natural and pertinent insertion into the doctor/patient relationship; this is captured in the test's "operational attributes".

The challenges faced to increase the use of patient questionnaires in clinical practice are significant. Among them, the need for patient questionnaires that have tangible consequences is central⁶. The PRAC-Test has the potential to contribute to the development of instruments truly adapted to health care professionals, addressing their needs and constraints, and to improve the acceptability of patient questionnaires by key opinion leaders and clinicians. It is available in two versions, and was rigorously designed according to standard methodology for questionnaire development. Moreover, comparison of different tools is now possible as it is a standardized test. As far as we are aware, no similar test exists. Nonetheless, certain limits of this tool should be noted: a certain bias may have been introduced as only general practitioners and specialists were interviewed. Further validation of the test should be carried out with other health-care professionals such as nurses. There is currently no scoring, and psychometric validation has not yet taken place. However, it should be noted that the test was not developed as a tool to be scored, but to support the systematic evaluation of the qualities and drawbacks of patient questionnaires for clinical practice. It can be used as it is, and with use over time a scoring system for the PRAC-Test could be discussed.

Conclusion

The PRAGmatic Content and face validity Test (PRAC-Test) is a promising aid for the development of tools for clinical practice. It can be used during development or in pilot testing, and can ensure the relevance of the tool to clinicians and general practitioners. A translatability assessment has been carried out, and a UK English version will be available shortly.

For further information, please contact:

Benoit Arnould
Mapi Values 27 rue de la Villette
69003 Lyon France
Tel: +33 (0)4 72 13 66 98
Fax: +33 (0)4 72 13 51 40
barnould@mapi.fr

For information on conditions for access to the PRAC-Test, please contact Caroline Anfray at the Mapi Research Trust, canfray@mapi.fr

- Morris J, Perez D, McNoe B. The use of quality of life data in clinical practice. *Qual Life Res* 1998; 7, 85-91
- Nelson E, Berwick D. The measurement of health status in clinical practice, *Med Care* 1989; 27 (3 Suppl): S77-90
- Golden WE. Health status measurement. Implementation strategies. *Med Care* 1992; 30 (5 Suppl):MS187-95; discussion MS196-209.
- Dennison C. The role of patient-reported-outcomes in evaluating the quality of oncology care, *Am J Manag Care* 2002; 8 (18 Suppl): S580-6
- Detmar S, Muller M, Schornagel J et al. Health-related quality-of-life assessments and patient-physician communication, A randomized controlled trial. *JAMA* 2002 18; 288 (23): 3027-34
- Rumsfeld J. Health status and clinical practice. When will they meet?, *Circulation* 2002; 106:5-7
- CDER2002193, docket no. 2006D-0044, Draft Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, February 2006 <http://www.fda.gov/cder/guidance/5460dft.pdf>
- European Medicines Agency. Reflection paper on the regulatory guidance for the use of Health-Related Quality of Life measures in the Evaluation of Medicinal Products, EMEA/CHMP/EWP/139391/2004
- Scientific Advisory Committee of the Medical Outcomes Trust. Assessing health status and quality of life instruments: attributes and review criteria, *Qual Life Res* 2002;11(3):193-205
- Chassany O, Sagnier P, Marquis P et al. Patient-Reported Outcomes: the example of health-related quality of life - a European guidance document for the improved integration of health-related quality of life assessment in the drug regulatory process, *Drug Inf J* 2002; 36: 209-238
- Arnould B. Patient-Reported Outcomes and Clinical Practice. From Measurement Instruments to Decision Tools: Much More than a Simple Change in Format, *PRO Newsletter* 2006; 36: 21-24.
- Schwartz G, Merriman M, Reed G et al. Evaluation of the Missoula-VITAS Quality of Life Index-Revised: Research Tool or Clinical Tool? *J Palliat Med* 2005; 8(1):121
- Bjorner JB, Kosinski M, Ware JE. Calibration of an item pool for assessing the burden of headaches: An application of item response theory to the Headache Impact Test. *Qual Life Res* 2003; 12(8): 913-33
- Bezak A, Taylor KM, Ng P et al. Quality-of-life information and clinical practice: the oncologist's perspective. *Cancer Prev Control* October 1998; 2(5): 230-5
- Lohr K.L. Applications of health status assessment measures in clinical practice. *Med Care* 1992 May; 30 (5 Suppl): MS1-14
- Wilson I, Cleary P. Linking clinical variables with health-related quality of life. *JAMA* 1995; 273 (1): 59-65
- Peterson R, Stevens JC, Ganguli, M et al. Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). *Neurology* 2001; 56: 1133-1142
- Evans C, Crawford B. Patient self-reports in pharmaco-economic studies. *Pharmacoeconomics* 1999; 15 (3): 241-56
- De Dombal F. Medical diagnosis from a clinician's point of view. *Methods Inf Med* 1978; 17 (1): 28-35
- Duffy C. Measurement of health status, functional status, and quality of life in children with juvenile idiopathic arthritis: clinical science for the pediatrician. *Pediatr Clin North Am* 2005; 52: 359-372
- Greenfield S, Nelson E. Recent developments and future issues in the use of health status assessment measures in clinical settings. *Med Care* 1992; 30 (5 Suppl): MS23-41
- Wright E, Selby P, Crawford M et al. Feasibility and compliance of automated measurement of quality of life in oncology practice. *J Clin Oncol* 2003; 21 (2): 374-82
- McHorney C, Tarlov A. Individual-patient monitoring in clinical practice: are available health status surveys adequate? *Qual Life Res* 1995; 4: 293-307
- Willke R, Burke L, Erickson P. Measuring treatment impact: a review of patient-reported outcomes and other efficacy endpoints in approved product labels. *Control Clin Trials* 2004; 25: 535-552
- Ragab A. Validity of self-assessment outcome questionnaires: patient-physician discrepancy in outcome interpretation. *Biomed Sci Instrum* 2003; 39: 579-584
- Evans C, Trudeau E, Mertzanis P et al. Development and validation of the pain treatment satisfaction scale: a patient satisfaction questionnaire for use in patients with chronic or accurate pain. *Pain* 2004; 112: 256-266
- Marquis P, Chassany O, Abetz L. A comprehensive strategy for the interpretation of quality of life data based on existing methods. *Value Health* 2004; 7 (1): 93-104
- Paul S. Developing practice protocols for advanced practice nursing. *AACN Clin Issues* 1999; 10 (3): 343-55
- Jagsch R, Pils K. Which instrument is more suitable to assess health-related quality of life: Nottingham Health Profile or Short-Form-36? *Wien Med Wochenschr* 2006; 156:149-157
- Zou G. From diagnostic accuracy to accurate diagnosis: interpreting a test result with confidence. *Med Decis Making* 2004 May-Jun; 24 (3): 313-8
- Meers C, Singer M. Health-related quality of life assessment in clinical practice, *J CANN T* 1996 Spring; 6(2): 29-31
- Streiner D, Norman G. Health measurement scales. A practical guide to their development and use. Oxford University Press, 1989
- Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington, D.C.: National Academy Press, 2001
- Berwick D. Disseminating Innovations in Health Care, *JAMA*, 2003; 289(15): 1969-75

Acknowledgments

The authors wish to thank Marc Vigneux, Khadra Benmedjahed, Sylvie Dard and Laurence Prost for their contributions to the development of the PRAC-Test.