Chapter 2: METHODS

This chapter briefly summarises the methods used to find the evidence used to inform the various reviews included in this report, together with principles for inclusion and exclusion of evidence. The ways in which evidence was judged is also briefly described.

a) Search strategy

The search strategy was designed to retrieve references relating to patient-reported health instruments for each of the disease groups in this review: that is, Asthma (Chapter 4), COPD (Chapter 5), Diabetes (Chapter 6), Epilepsy (Chapter 7), Heart failure (Chapter 8) and Stroke (Chapter 9). Chapters 10 and 11 report reviews of Carer impact health instruments and Patients perceptions of quality.

Hosted by the National Centre for Health Outcomes Development (NCHOD) at the University of Oxford, the Patient-reported Health Instruments (PHI) website (http://phi.uhce.ox.ac.uk/) includes a bibliography of over 12,000 records relating to published instrument evaluations found on the following electronic databases: Allied and Alternative Medicine (AMED), Biological Abstracts, British Nursing Index, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Econlit, EMBASE, Medline, PAIS International, PsycInfo, System for Information on Grey Literature in Europe (SIGLE), and Sociological Abstracts. At the time of this review, the bibliography comprised references up to June 2005. Details of the search strategy for the bibliography are available on request. The primary search of the bibliography used the terms specific to each disease group, as detailed in each review chapter secondary search of the database used the names of identified instruments.

Additional searching included:

The reference lists of included records were reviewed for additional articles. Hand searching of the following journals was carried out:
-Quality of Life Research
-Health and Quality of Life Outcomes
-Medical Care
Other journals specific to the review disease groups were also hand searched.

Where available, websites designated to the included instruments were identified. Listed references were assessed for inclusion and supplementary information summarised.

b) Inclusion criteria

Titles and abstracts of all articles were assessed for inclusion/exclusion by two independent reviewers and agreement was checked. Included articles were retrieved in full. Published articles were included if they provided evidence of measurement and/or practical properties (Fitzpatrick et al., 1998) for multi-item instruments assessing aspects of health status or quality of life in patients with asthma, COPD, diabetes, epilepsy, heart failure and stroke.

Specific inclusion criteria for generic and disease-specific instruments

- The instrument is patient-reported
- There is published evidence of measurement reliability, validity or responsiveness following completion in the specified patient population
- The instrument has been recommended for use with patients with asthma, COPD, diabetes, heart failure, epilepsy or stroke
- The instrument provides English-language versions for use among adult patients from UK, North America and Australia.
- Evidence is available from English language publications, and instrument evaluations conducted in populations within UK, North America, Australasia.

Exclusion criteria

Clinician-assessed instruments,

- Very narrowly focused or single-item instruments
- Instruments only measuring symptoms
- Instruments without empirical evidence of measurement properties.

c) Data extraction

Data extraction followed pre-defined criteria and included both study-specific issues, such as study design and respondent characteristics, and instrument-specific issues, for example, type and description of instrument, including the domains of health status covered response format, length, and evidence of measurement and practical properties (McDowell and Newell., 1996; Fitzpatrick et al., 1998; Garratt et al., 2002).

d) Format of the reviews

The summary of evidence follows that of previous reviews (McDowell and Newell., 1996; Fitzpatrick et al., 1998; Haywood et al., 2004). Detailed reviews of generic and disease-specific instruments are found in Chapters 4 to 11. The following information is provided for each instrument:

Title

The instrument title as given by the original developer. Instrument developers, year of original publication, and subsequent revision.

Description

The purpose and proposed application of each instrument as defined by the developers.

Instrument development, including item derivation, is summarised where available. Instrument content, the domains of health status covered, for example, pain and social well-being, the number of items, response options, and method of scoring are reported. Instrument modifications are described.

Study specific information

Measurement properties are specific to the population and setting in which an instrument is used (Streiner and Norman., 1995; Fitzpatrick et al., 1998). Study-specific information relating to study design and setting, for example, whether the assessment was carried out in a primary care setting, out-patients or in-patients, population characteristics including inclusion/exclusion criteria, intervention(s), duration of the study and follow-up, and mode of questionnaire administration, informs the interpretation of instrument performance and clinical usefulness. Study-specific information summarises population and study characteristics, for example, age, sex, etc.

Measurement properties

For all instruments published evidence of measurement properties is summarised under the following sub-headings:

- reliability
- validity: i. socio-demographic variables and health-service use
  ii. construct validity: other instruments
  iii. other types of validity
- responsiveness
- precision

Practical properties

Where available, published evidence of acceptability and feasibility is summarised.

Tables summarizing the studies that provide evidence for each included instrument take the following form. A tick (✓) is used to indicate that some minimal level of positive evidence was reported within the study supporting the relevant instrument.

e) Review summaries

Evidence for measurement and practical properties was assessed using accepted criteria (Streiner and Norman, 1995; McDowell and Newell, 1996; Fitzpatrick et al., 1998) (detailed in Chapter 1).

Fitzpatrick et al., (1998) list the domains of health status most frequently identified in the literature as relevant to patient-reported health instruments, as shown in Table 2.1. To support comparison between instruments, instrument content was reviewed against this general classification.

The number of studies in which the instrument has been evaluated is provided; where several publications relate to the same study population, this is indicated.

Although there are relatively clear cut and widely agreed criteria available to assess measurement properties of instruments, there are no clear-cut explicit criteria for how to weigh the balance of evidence or weigh the balance of evidence for instruments comparatively. The reviews reported here are based on weighing up for each of the instruments considered in detail: the volume of available evidence, the quality of studies and, ultimately, the overall extent of positive and supportive evidence of measurement properties and feasibility. To some extent the reviews should be considered as based on a form of 'rapid appraisal'. They were written to inform current and pressing policy initiatives in a prompt and timely fashion. Although we are confident that we have a reasonably up-to-date and representative body of evidence to inform recommendations, in the time available it was not feasible exhaustively to search more inaccessible evidence. Nor was there time or resource to test recommendations against a consensus process of relevant user, professional and scientific judgements.

Table 2.1 Domains of health most commonly assessed in patient-reported health instruments.

I Physical Function Mobility, dexterity, range of movement, physical activity Activities of daily living: ability to eat, wash, dress	
II Symptoms Pain Nausea Appetite	Energy, vitality, fatigue Sleep and rest
III Global judgements of health	
IV Psychological well-being Psychological illness: anxiety, depression Coping, positive well-being and adjustment, sense of control, self-esteem	
V Social well-being Family and intimate relations Social contact, integration, and social opportunities Leisure activities Sexual activity and satisfaction	
VI Cognitive functioning Cognition Alertness Concentration	Memory Confusion Ability to communicate
VII Role activities Employment Household management	Financial concerns
VIII Personal constructs Satisfaction with bodily appearance Stigma and stigmatising conditions Life satisfaction Spirituality	
IX Satisfaction with care	

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