

HEALTH STATUS AND QUALITY OF LIFE (QoL) IN MYALGIC ENCEPHALOPHTHY / CHRONIC FATIGUE SYNDROME (ME/CFS): A STRUCTURED REVIEW OF PATIENT-REPORTED OUTCOME MEASURES (PROMS)

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Introduction

ME/CFS is a long-term, disabling condition, profoundly affecting health and QoL. Its course is unpredictable, often fluctuating.

Its prevalence is estimated as 0.2-0.4% [1], i.e. up to 240,000 people in the UK. A recent study estimated annual direct and indirect costs to be £6.4 billion [2].

Communicating the impact of ill-health and associated healthcare requires relevant and appropriate information. The patient's experience and expertise regarding health and healthcare is an essential resource, recognised as an important determinant of overall treatment effectiveness [e.g., 3].

Well developed PROMs, often multi-item questionnaires, are an essential part of health care assessment, providing an accessible and meaningful mechanism by which patients may communicate the impact of ill-health and associated health care [4,5].

As a result of the increasing focus on patient-reported health there are now several hundred PROMs available, and for many health states there is often a choice; moreover, there is often little consensus about which PROMs clinicians should use.

Structured reviews of essential measurement and practical properties are a prerequisite for PROM selection and standardisation.

This review evaluates published evidence for multi-item PROMs applied in evaluations of patients with ME/CFS and will guide future PROM selection for use in research, routine practice and quality assessment.

Objectives

1. To identify ME/CFS-specific, domain-specific and generic PROMs applied in the assessment of people with ME/CFS
2. To extract and assess evidence relating to PROM development and evaluation.

Methodology

Identification of studies

Search strategy to retrieve references relating to the development and evaluation of multi-item PROMs (1980-May 2006).

Search terms specific to ME/CFS combined with terms relevant to health measurement: MeSH and free text searching. Additional searches used names of identified PROMs.

Inclusion/Exclusion criteria

Titles/ abstracts assessed by two independent reviewers (KH, SC); agreement checked. Published articles included if they provided evidence of measurement properties for multi-item PROMs following completion by adults with ME/CFS.

Clinician-assessed measures, single-item and mobility measures, radiographic and imaging techniques were excluded.

PROMs without evidence of reliability or validity were excluded.

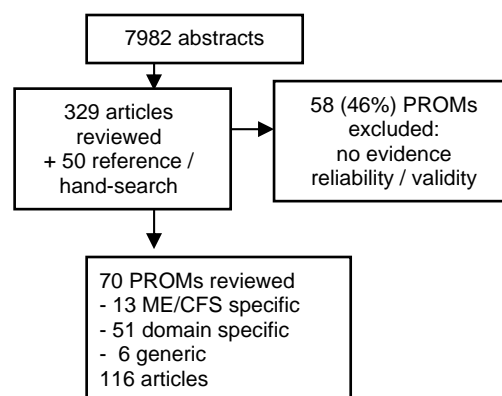
Data extraction

Followed pre-defined criteria considered important in PROM evaluation [e.g., 6]:

- Patient characteristics
- PROM type, domain focus, scaling, length.
- Measurement properties: reliability, validity, responsiveness
- Practical properties: appropriateness, feasibility, acceptability
- Evidence of patient involvement in PROM development and evaluation.

Two reviewers; acceptable reliability

Results



Patient and study characteristics

Sample sizes generally small (range 15 to 258 patients). Mean age ranged 15.5 yrs to greater than 50 yrs. Most patients diagnosed according to the CDC 1994 Fukada criteria.

Key findings

Discrepancy between patient important outcomes (PIO) and what is measured

PIOs include fatigue, social well-being, physical disability and general well-being. (PRIME1*)

Most widely assessed outcomes - emotional well-being, fatigue, sleep dysfunction.

Large number of poor quality PROMs

Majority had limited evidence of essential measurement and practical properties. Few comparative evaluations. Most ME/CFS-specific PROMs only evaluated by developers. Recommendations difficult.

High quality PROMs not identified; therefore high quality evidence of treatment effect not exist – difficult to inform treatment choice.

Lack of standardisation and co-ordination

Re WHAT is measured and HOW it is measured.

Poor reporting of PRO assessment

Many assessments not reproducible - lack of reference or detail – therefore not reviewed.

Minimal patient involvement

In item generation or evaluation poor; where reported, patient involvement is minimal.

No published studies evaluating patients' views of published PROMS – for example, relevance and acceptability. Lack of appropriate qualitative research

ME/CFS-specific PROM

No PROM effectively reflects the concerns of patients, demonstrates patient involvement throughout its development, and has appropriate scientific rigor to support application in clinical trials.

Challenges / Future Research

Consensus re PIO and PROMs

Achieve consensus on WHAT should / could be measured and HOW it should / could be measured – to identify outcomes that better capture patient experience.

Core outcomes

Core outcomes and associated measures of relevance to patients and health professionals for application in clinical research, routine practice and quality assessment.

Highlight gaps for future research.

Comparative evaluation

Rigorous assessment and reporting of measurement and practical properties of recommended PROMs.

Promote appropriate reporting of key outcomes in research

Clarity in reporting; support interpretation and reproduction of study results.

Active patient involvement

Require collaboration between patients, researchers, health professionals in future PROMs-related research.

Move towards patient partnership?

Consultation – historically
Collaboration – in different parts of the study
User-led - the future?

PRIME* - Partnership for Research in ME/CFS

ME/CFS-specific health

Develop a ME/CFS-specific PROM that reflects patients concerns, involves patients and professionals throughout the development process, and has rigorous scientific measurement properties.

References

1. DH Rept ME/CFS Work Grp 2006;
2. AfME Rept 2006; 3. High Quality Care for All. 2008; 4. Greenhalgh (2005) Soc Sci Med 60:833; 5. Haywood (2006) Pt Edu Couns 63:12. 6. Fitzpatrick (1998) HTA Report.

***Web-links: PRIME Partnership for Research in ME/CFS:** a collaboration between patients, carers, researchers and service providers who share a commitment to improving our understanding of ME/CFS <http://www.prime-cfs.org/>