



Qualitative methods in PRO research: development of a methods matrix

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Background

FDA draft guidance highlights the importance of patient input in PRO research. Qualitative research methods can provide this patient input.

Many different qualitative methods are used in health and social research.

These include qualitative data collection methods, for example:

- individual interviews (e.g. narrative, semi-structured, cognitive)
- focus groups
- text (e.g. personal narratives, policy documents, literature, meeting minutes)
- naturally occurring dialogue (e.g. consultations, meetings)

They also include qualitative analysis methods, for example:

- thematic analysis
- content analysis
- grounded theory
- discourse analysis
- hermeneutic analysis
- interpretative phenomenological analysis (IPA)

Different PRO research tasks have different aims. The FDA draft guidance advocates certain methods of qualitative data collection: patient interviews (including cognitive debriefing interviews) and focus groups. However, the guidance gives little direction over qualitative analysis methods or which qualitative research methods are suitable for specific PRO research tasks.

Objectives

To review qualitative methods used in PRO research and to develop a matrix relating appropriate methods to PRO research areas and tasks.

Methods

A literature search was conducted to identify qualitative research methods applied to PRO research since the publication of the FDA draft

guidance in February 2006. Firstly Medline searches were carried out on publications 2006 onwards and combined PRO and quality of life terms with general and specific qualitative data collection and analysis terms. Secondly, three journals known for publishing PRO research (*Quality of Life Research*, *Health and Quality of Life Outcomes*, *Value in Health*) were hand-searched for relevant publications in the last 3 years.

Aim of PRO research task, data collection and analysis methods were noted for each example of qualitative research methods applied to PRO research identified. A matrix relating appropriate qualitative methods to type of PRO research was then developed from this record and a wider critical appraisal of the studies. Where possible, this critical appraisal considered the requirements for valid and reliable PRO and qualitative research.

The distinction between qualitative data collection and analysis methods means there is potential for different combinations of data collection, analysis and PRO tasks (i.e. a 3-dimensional matrix). For simplicity two separate matrices were developed, one for qualitative data collection and one for qualitative analysis.

Results

- The application of qualitative research methods in PRO research has been widespread in recent years. However, methods for qualitative data were more commonly reported than methods for qualitative analysis.
- It was common for methods such as cognitive debriefing, patient interviews, patient focus groups, content analysis to be named without further detail or description. Where this was the case, qualitative methods were not reported in sufficient detail for critical appraisal.
- This means that the resulting matrices were based more on a quantitative assessment of main methods used, rather than a critical appraisal of studies against PRO and qualitative research requirements.

Qualitative data collection methods in PRO matrix

PRO Task	Semi-structured interview	Cognitive interview	Focus group	Text
Development of conceptual model	√		√	√
Selection of PRO	√	√	√	
Development of PRO	√	√	√	√
Linguistic validation		√		
Assessment of content validity	√	√	√	

Qualitative analysis methods in PRO matrix

PRO Task	Grounded Theory	Thematic analysis	Content analysis
Development of conceptual model	√	√	√
Selection of PRO		√	√
Development of PRO	√	√	√
Linguistic validation		√	√
Assessment of content validity		√	√

Conclusions

There is a widespread and increasing use of qualitative research methods in PRO research seen in recent years. From published reports it was possible to match common qualitative research methods to different types of PRO research tasks.

However, development of a methods matrix by critically appraising this literature was hampered by the lack of detail reported in publications. Methods of qualitative data collection were often named without any further explanation or methodological detail. Where qualitative data had been collected, methods of qualitative analysis were often not stated. This may simply be a result of word limit restrictions introduced by journals. It may be unrealistic to expect papers reporting the full process of development and validation of PRO measure to be able to devote much space to qualitative methods. The lack of detail may mean that although qualitative methods were named they may not have been meaningfully or rigorously used.