Collating the evidence base to facilitate patient and public involvement in core outcome set development – a qualitative meta-synthesis

Challenges of conducting a methodology review

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What is a core outcome set?

A core outcome set (COS) is a standardised set of outcomes which should be measured and reported, as a minimum, in all effectiveness trials for a specific health area.

Why should we do this?

1. Heterogeneity of outcomes
2. Publication Bias
3. Outcomes not reflecting what is important to patients
4. Waste in health research

Hopewell et al. 2009
Public & patient input in COS development

**Involvement:** The public and patients can be involved in a COS study as a research partner, co-investigator, advisor, or research team member. In this role they will help in the design and progression of a core outcome set study.

**Participation:** As patient participants in your COS study – contributing to the results of your study, i.e. completing your survey or taking part in interviews, attending consensus meetings

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Aims of the qualitative meta-synthesis

1. To characterise the literature
2. To explore the ways in which studies have reported PPI
3. The context in which PPI was employed

Collating the evidence to inform guidance on how best to involve patients - one of the key stakeholders in COS development.

Meta-synthesis involves the integration of themes from numerous qualitative studies; the technique is interpretive and yields findings that are “greater than the sum of the parts”.

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Public and patient involvement in COS and patient reported outcome measures development

**COMET database**

The COMET database currently contains 835 references of planned, ongoing and completed work.

- **Search**

Enter Keyword

The keyword used for the search will be compared with study title, abstract and author's surname.

View full search options

To view a demonstration of how to search the COMET database click [here](#)

**PROM search**

- MEDLINE
- PsycINFO
- HaPI (health and psychosocial instruments)
- Cochrane Methodology
RESEARCH ARTICLE

The Importance of Integration of Stakeholder Views in Core Outcome Set Development: Otitis Media with Effusion in Children with Cleft Palate

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Background
Approximately 75% of children with cleft palate (CP) have Otitis Media with Effusion (OME) histories. Evidence for the effective management of OME in these children is lacking. The inconsistency in outcome measurement in previous studies has led to a call for the development of a Core Outcome Set (COS). Despite the increase in the number of published COS, involvement of patients in the COS development process, and methods to integrate the views of patients and health professionals, to date have been limited.

Methods and Findings
A list of outcomes measured in previous research was identified through reviewing the literature. Opinion on the importance of each of these outcomes was then sought from key stakeholders. For National Health (NHS) and Charitable Trust organisations, a Delphi survey was conducted, and participants were asked to score each outcome using a bespoke online system. Parents and children were also asked to score outcomes in a survey and provided an in-depth insight into having OME through semi-structured interviews. The results of the Delphi survey, interviews and parent/patient survey were brought together in a final consensus meeting with representation from all stakeholders. A final set of eleven outcomes reached the definition of “consensus in” to form the recommended COS: hearing; chronic otitis media (COM); OME; receptive language skills; speech development; psycho social development; acute otitis media (AOM); cholesteatoma; side effects of treatment; listening skills; otalgia.

Conclusions
We have produced a recommendation about the outcomes that should be measured, as a minimum, in studies of the management of OME in children with CP. The development process included input from key stakeholders and used novel methodology to integrate the opinion of healthcare professionals, parents and children.
A patient representative was approached during the study and accepted membership of the SAG but then, due to unforeseen personal circumstances, needed to withdraw from membership prior to attending an SAG meeting. The SAG and also the Study Steering Committee (SSC, comprising a trial methodologist, patient representative, health economist and a paediatric otorhinolaryngologist) were also given the opportunity to add outcomes to the list that they considered important.
Citizen panel
Patient Participation
Patient Advocacy
Consumer Participation
Consumer Advocacy
Lay PE Public
Consultation
Input
Stakeholder
Client
Parent
Perspective
Engagement
Participates
Public forum
Customer
Developer
Involvement
Representatives
Consumer Organizations
Patient
Service user
Care
PPI
User
Public and Patient Involvement
Relative
Collaborators
Patient Organisation
How can we overcome these problems?
Review of “randomised controlled trials assessing methods for involving consumers”

**MEDLINE search strategy**

1. Consumer Participation/
2. Patient Participation/
3. Consumer Advocacy/
4. Consumer Organizations/
5. Public Opinion/
6. ((consumer? or patient? or stakeholder? or user? or lay or citizen? or public or client?) adj (particip$ or involv$ or represent$ or collaborat$ or consult$ or contribut$ or engagement or deliberat$ or dialogue or opinion?)).tw.
7. (citizen$ adj (council? or jury or juries or panel?)).tw.
8. (public adj (meeting? or forum?)).tw.
9. participatory intervention?.tw.
10. ((consumer? or patient?) adj organi#ation?).tw.
Main results A total of 189 studies, describing the development of 193 PROMs, were included. Most PROMs were meant for chronic disease patients \((n = 59)\) and measured quality of life \((n = 28)\). In 25.9\% of the PROM development studies, no patients were involved. Patients were mostly involved during item development (58.5\%), closely followed by testing for comprehensibility (50.8\%), while patient involvement in determining which outcome to measure was minimal (10.9\%). Some patient involvement took place in the development of most PROMs, but in only 6.7\% patients were involved in all aspects of the development. Patient involvement did not increase with time.
Moving forward