Patient and public participation and involvement in COS development

Bridget Young & Heather Bagley, University of Liverpool
Why seek patient input in COS?

“Sometimes people can assume that they know what outcomes are important and actually they’re completely different from the ones that patients feel are necessary.”

Rosanna Preston (Former Chief Executive, The Cleft Lip and Palate Association)
### Patient participation versus involvement

<table>
<thead>
<tr>
<th>Participation – patients contribute data to COS studies</th>
<th>Involvement – patients input to planning/design of COS studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified “real, wide-ranging problems that we currently do not assess”</td>
<td>“Clear guidance for what was acceptable and relevant”</td>
</tr>
<tr>
<td>“Enabled the patient voice to be heard throughout the COS development process”</td>
<td>“Part of the writing team”</td>
</tr>
</tbody>
</table>

Both patient participation and involvement helped to keep “the values of patients high on the agenda”

What patient input are COS developers seeking?

**Participation**

- 63/264 (24%) COS published up to end of 2014 had patient participants
- 171/189 (91%) ongoing COS plan to include patient participants

**Involvement**

- Rates of patient involvement not known
- Participation and involvement often blurred
  (Gargon *JCE* 86 2017, 140-152)
We’re interviewing patients/members of the public for qualitative study to inform guidance on patient and public involvement in COS studies.

Can you help us access interviewees?

Is your COS study **completed** or **close to completion**?

Did a patient/member of the public **input or advise on the design or running** of your COS study?

If yes, please get in touch!

**Lucy Brading**

**Lbrading@liverpool.ac.uk**
How patients participate in COS?

- Delphi surveys
- Consensus meetings, workshops, discussions
- Qualitative studies (focus groups or interviews)
Patient participation in COS via qualitative studies

• Part of wider multi-method COS study
• Enable patients to participate in own terms
  – Identify outcomes not captured by other methods?
• Inform Delphi/consensus process
• Inform consensus deliberations
• But needs resource and expertise
• Collect new qualitative data vs systematic reviews of published qualitative studies*

Ethics – UK position

• HRA: If the aim is to produce generalisable knowledge, COS development is research and like any research requires ethical review
  – Likely applies for all participants.
  – (Ethical review not needed for involvement of patients/public in design/planning of COS studies)

• Who should review - NHS REC or other body e.g. university?
  – Depends on how you plan to identify participants - see HRA decision tool http://www.hra-decisiontools.org.uk/ethics/.

• If NHS ethics is required a proportionate review may suffice, although some COS developers have had to seek full review

COMET Resource: Research ethics considerations for COS studies with patients http://www.comet-initiative.org/ppi/researchers
Patient Participation in COS - Some key challenges

- Understanding COS & the need for COS
- Patient perceptions of COS
- Language
- Patient input into COS studies
- International COS
Outcome? ...... I just want to be cured!

Important outcomes? ...... They’re all important!
Surely you know already which outcomes are important to us!

“Patients assume that researchers must know what’s important to them and COS would have been sorted out a long time ago”. Humphreys 2014 (Public research partner)
Tinnitus COS animation
Taking part in a COS study

• “Scientific studies are always a bit daunting ... you may sort of think that your opinion doesn’t count for anything or that maybe you don’t have the same opinion as somebody else ... so you’re complaining .... or what you’re talking about is just not important.” Jo Hossell (parent COS participant).

• Developing an interest in a COS study
• Explaining the process of a COS study

(Delphi plain language summary: http://www.comet-initiative.org/resources/PlainLanguageSummary)
Consensus meetings

- Appropriate planning and support for patients in consensus meetings

COMET Resource: **Tips for Designing an Accessible Core Outcome Set Consensus Meeting**

Preparation for a Consensus Meeting

- Ensure that costs for public participants in consensus meetings are planned for. For information about using core outcome set processes, see section 2.15 of the COMET Handbook.
- Address the public as early as possible. The meeting can help to involve them in all aspects of the COS study. Early engagement can help to ensure that all aspects of the outcome set are accessible and participatory. Many patients may have never participated in this type of meeting before. Involving public and patient representatives in the planning of the meeting can help to ensure that all aspects of the COS study are accessible and participatory.

Patient & Public Involvement in the Design of your COS Study

- Get public research partners involved as early as possible. They can help you design your core outcome set study. Early engagement can help to ensure that all aspects of the study are accessible and participatory. Many patients may have never participated in this type of meeting before. Involving patients and public representatives in the planning of the meeting can help to ensure that all aspects of the COS study are accessible and participatory.

Preparation for a Consensus Meeting

- Consider who to invite.
  - Ensure that costs for public participants in consensus meetings are planned for. For information about using core outcome set processes, see section 2.15 of the COMET Handbook.
  - Address the public as early as possible. The meeting can help to involve them in all aspects of the COS study. Early engagement can help to ensure that all aspects of the outcome set are accessible and participatory. Many patients may have never participated in this type of meeting before. Involving public and patient representatives in the planning of the meeting can help to ensure that all aspects of the COS study are accessible and participatory.

For more information, visit [http://www.comet-initiative.org/ppi/researchers](http://www.comet-initiative.org/ppi/researchers)
Patient and Public involvement in a core outcome set (The MOMENT study)

This video explains the involvement and participation of parents, young people and a patient organisation in a core outcome set study.

Management of Otitis Media with Effusion in children with Cleft Palate

Investigative Team:
Professor K O'Brien
Professor P Williamson
Professor P Callery
Professor W Shaw
Professor K Payne
Professor I Bruce
Dr N Harman
Stephanie Tierney

Harman NL, Bruce IA, Callery P, Tierney S, Owais Sharif M, O'Brien K, Williamson PR
Trials 2013; 14 (1):70 (Epub) (PMID 23497540)

I Bruce, N Harman, P Williamson, S Tierney, P Callery, S Mohiuddin, K Payne, E Fenwick, J Kirkham, K O'Brien
The management of Otitis Media with Effusion (OME) in children with Cleft Palate: A feasibility study and economic evaluation. (mOMENT)
NIHR HTA programme

MOMENT was funded by the NIHR HTA programme
International COS

- Ethics
- Language
- Culture
- Funding
- Infrastructure

International PPI Network
Breakout groups

• Focus on *patient participation* in COS Delphis/consensus meetings, also how *patient involvement* in design/running of COS can help

• 4 groups of ~10 people, 3 questions per group

• Brief feedback – 2-3 minute headlines per group
Breakout group - questions

1. How can you involve patients and the public in helping you design and oversee your COS study?
2. What principles and practicalities are important in identifying and sampling patients participants?
3. Ways of explaining concept of outcome/COS?
4. How to design Delphis to enable meaningful patient participation?
5. How to design and prepare for consensus meetings to enable meaningful patient participation?
6. What are the challenges of running an international COS with patient participants and how might you overcome them?