Patient and public participation and involvement in COS development

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Why seek patient input in COS?

Rosanna Preston (Former Chief Executive, The Cleft Lip and Palate Association)

“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.”

Patient participation versus involvement

Participation – patients contribute data to COS studies	**Involvement – patients input to planning/design of COS studies**
Identified *“real, wide-ranging problems that we currently do not assess”*	*“Clear guidance for what was acceptable and relevant“*
“Enabled the patient voice to be heard throughout the COS development process”	*“Part of the writing team”*
Both patient participation and involvement helped to keep *“the values of patients high on the agenda”*	

Haywood et al Public Involvement in Developing a Core Outcome Set for Cardiac Arrest Clinical Trials: COSCA initiative - http://www.oxfordahsn.org/wp-content/uploads/2017/01/K-Haywood-Outcomes-that-matter-slides.pdf

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!

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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*

*Keeley et al *Trials* 2016 **17**:230; Hashem et al *Critical Care* 2016 **20**:345

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

Understanding COS

Outcome? …… I just want to be cured!

Important outcomes? …… They're all important!

COMET / COS Plain Language Summary - [**http://www.comet-initiative.org/resources/PlainLanguageSummary**](http://www.comet-initiative.org/resources/PlainLanguageSummary)

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).

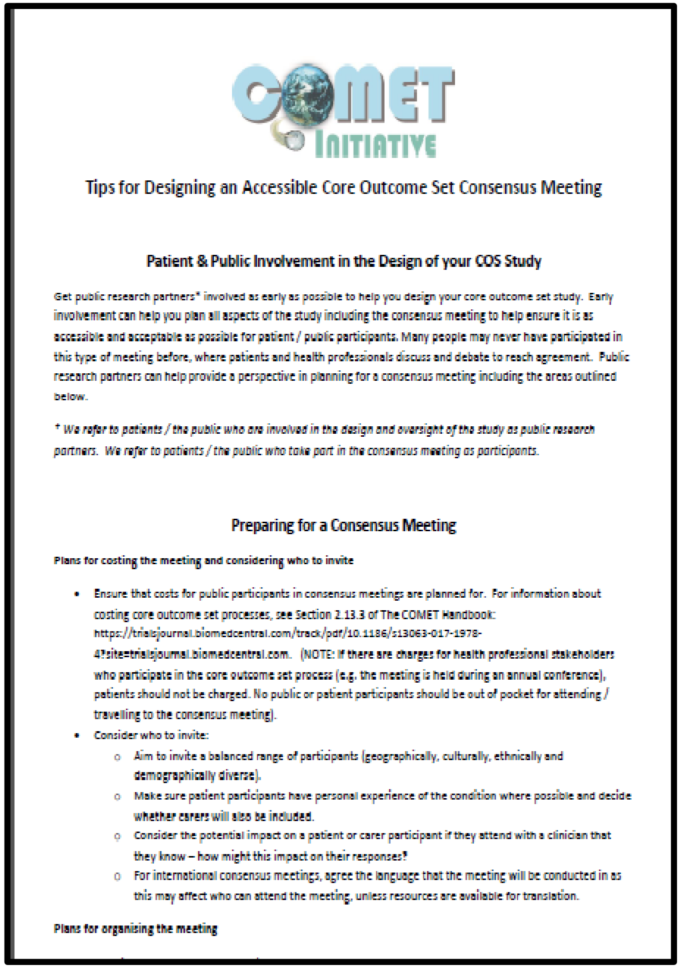
- Developing an interest in a COS study
- Explaining the process of a COS study

(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** http://www.comet-initiative.org/ppi/researchers



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Tips for Designing an Accessible Core Outcome Set Consensus Meeting

Patient & Public Involvement in the Design of your COS Study

Get public research partners* involved as early as possible to help you design your core outcome set study. Early involvement can help you plan all aspects of the study including the consensus meeting to help ensure it is as accessible and acceptable as possible for patient / public participants. Many people may never have participated in this type of meeting before, where patients and health professionals discuss and debate to reach agreement. Public research partners can help provide a perspective in planning for a consensus meeting including the areas outlined below.

** We refer to patients / the public who are involved in the design and oversight of the study as public research partners. We refer to patients / the public who take part in the consensus meeting as participants.*

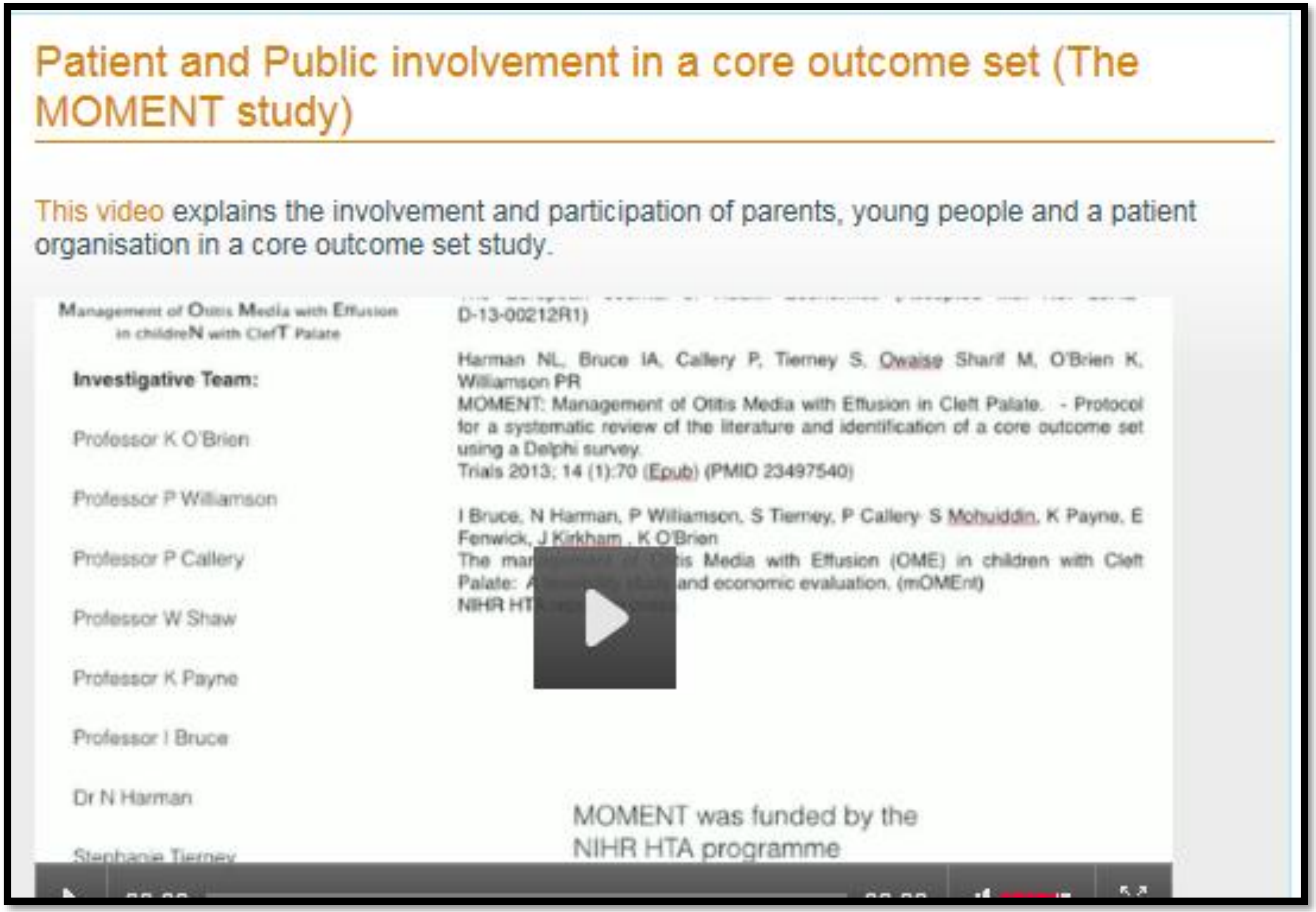
Preparing for a Consensus Meeting

Plans for costing the meeting and considering who to invite

- Ensure that costs for public participants in consensus meetings are planned for. For information about costing core outcome set processes, see Section 2.13.3 of The COMET Handbook: https://trialsjournal.biomedcentral.com/track/pdf/10.1186/s13063-017-1978-4?site=trialsjournal.biomedcentral.com. (NOTE: If there are charges for health professional stakeholders who participate in the core outcome set process (e.g. the meeting is held during an annual conference), patients should not be charged. No public or patient participants should be out of pocket for attending / travelling to the consensus meeting).
- Consider who to invite:
  - Aim to invite a balanced range of participants (geographically, culturally, ethnically and demographically diverse).
  - Make sure patient participants have personal experience of the condition where possible and decide whether carers will also be included.
  - Consider the potential impact on a patient or carer participant if they attend with a clinician that they know – how might this impact on their responses?
  - For international consensus meetings, agree the language that the meeting will be conducted in as this may affect who can attend the meeting, unless resources are available for translation.

Plans for organising the meeting

http://www.comet-initiative.org/resources/publicinvolvement



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

D-13-00212R1)

Harman NL, Bruce IA, Callery P, Tierney S, Owaise Sharif M, O'Brien K, Williamson PR
MOMENT: Management of Otitis Media with Effusion in Cleft Palate. - Protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey.
Trials 2013; 14 (1):70 (Epub) (PMID 23497540)

I Bruce, N Harman, P Williamson, S Tierney, P Callery S Mohuiddin, K Payne, E Fenwick, J Kirkham , K O'Brien
The mar is Media with Effusion (OME) in children with Cleft Palate: A and economic evaluation. (mOMEnt)
NIHR HT

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?