

## **The COMET / International PPI Network Webinar – Questions and Answers**

**Question 1 - Are there any groups (PPI) in Australia involved in General Surgery specialty conditions like hernia surgery or colorectal operations?**

**Answer** - We are not currently aware of any.

**Question 2 – I am interested in collaborating / getting involved with the COMET Initiative – what should I do?**

**Answer** - COMET would be happy to have a discussion with anyone interested in collaborating with COMET / PoPPIE.

- If your interest is about including patients in COS development, please email Heather Bagley, the COMET Patient and Public Involvement Co-ordinator [heather.bagley@liverpool.ac.uk](mailto:heather.bagley@liverpool.ac.uk)
- If your interest is more about core outcome set development in general please email the COMET Co-ordinator Liz Gargon: [gargon01@liverpool.ac.uk](mailto:gargon01@liverpool.ac.uk)

**Question 3: How diverse are patients who participate in the Core Sets definition?**

**Answer** - The COMET systematic reviews of published core outcome sets explore who the stakeholder groups were in the COS but don't cover more detailed information such as the demographics of the different stakeholder groups. The COMET Handbook recommends that core outcome set developers "adopt strategies to ensure that a diverse range of opinions is heard."

**Question 4: If there is any disagreement between healthcare workers and patients during the consensus meeting, I am wondering, how do you handle it? Did you experience any such things in your experience? If so, how did you handle it?**

**Answer** - The key is that everybody goes into such a meeting recognising that actually they might not agree about everything and that doesn't matter. It's about finding what everybody does agree about and then having good discussions, well facilitated by somebody who is independent. Well facilitated discussion about different points of views, respecting those different points of views and at the end of the meeting, if there is disagreement about a particular outcome, then in a transparent way, those results should be written up. We must remember that a core outcome set is a minimum set of outcomes that should be measured and reported everywhere so it is more than possible that in particular clinical trials some of the outcomes that one or other stakeholder group thinks is important, will be measured anyway. But from experience of meetings, almost everybody leaves the meeting feeling like our patient on the webinar said, thinking that they had a chance to speak, air their views, it was great to hear the discussion and sometimes that discussion is that we agree to disagree well.

**Question 5 - With all these outcomes for one issue does this mean funders need to do more perhaps by defining outcomes they are interested in?**

**Answer** - Several funders around the world are recognising the importance of core outcomes and trying to achieve standardisation, because of course, they really want the research that they fund to be not just a stand-alone piece of research but to be used in subsequent systematic reviews of evidence and that won't be possible if everybody continues to measure different things. Of course, they also want it to really inform health care using outcomes that matter to the decision makers, including patients. So, several funders already recommend that researchers consider the use of a well-developed core outcome set, if it exists and they recommend that people look in the COMET database to see what there is at the moment or what there is ongoing.

If the question was about whether the funders themselves should then direct researchers, I think where the funding panel, (which obviously includes researchers and typically patients, or sometimes patients) feel that perhaps the team have not appropriately considered various stakeholder views, then I know as a trialist, that recommendations are made to the team and sometimes that recommendation may be to use a core outcome set that exists that perhaps the research team isn't aware of.

**Question 6 - If you were concerned that there was no core outcome set for your disease, how would you go about pushing for change?**

Answer -Begin by contacting patient groups (local, national and international) to see if there are any collaboration possibilities with researchers. (Find such organisations on the web or through local hospitals). Make sure that the research leads for the patient organizations, where they exist, understand the importance of core outcome sets and advocate for their development. Those who are heavily involved with research may not have heard of COS but when they learn of the value of them they very quickly come on board. For rare diseases and smaller organizations, this could mean being proactive in bringing this issue to the organisation. Provide examples of other organizations that had developed core outcome sets and the impact of these for research in that condition.

**Question 7 Are the Canadian Patient Partners living with a rare disease themselves?**

Answer - There were two co-investigators. One was an adult who had been living with a rare disease since childhood, but not an inherited metabolic disease. The other was the parent of a child with PKU, one of the two diseases under study. The Family Advisory Forum was made up of parents of children with inherited metabolic diseases.

**Question 8 – Amazed at different outcomes chosen in cancer trials - did I really hear 25.000?? do you have a reference for that?**

**Answer** - This relates to outcomes being measured at lots of different time points in lots of different ways. The reference is: (Hirsch et al JAMA Intern Med 2013, 173:972-979)

**Question 9: How can we develop a research agenda around the methods of outcome development that underpin core outcome sets?**

**Answer:** The [Trials Methodology Research Partnership \(TMRP\)](#) in the UK has established eight working groups, specialising in areas relevant to trial methodology, including a Working Group for outcomes. Within this Working Group there is a separate group working specifically on core outcome sets, including those with an interest in including patients in core outcome set development. Please contact the COMET Co-ordinator Liz Gargon for further information: [gargon01@liverpool.ac.uk](mailto:gargon01@liverpool.ac.uk)

**Question 10 - Are there examples, other than RA patient's identification of fatigue as a core outcome you can provide? would be nice to know how PPI in other conditions outcomes that matter has made a difference in what's being done now**

**Answer** – We are aware of other core outcome sets where including the patient perspective has made a difference, for example:

- A core outcome set for chronic pain was initially developed with health professionals. When patients were later included they specifically highlighted the importance of the following outcomes: fatigue; sleep; home and family care; social and recreational activities; interpersonal relationships; and sexual activities<sup>1</sup>.
- Whilst developing a core outcome set of treatments to prevent pre-term birth, the research team reported that including parents of pre-term babies really made a difference, as they identified longer term problems resulting from the child's nervous system development that should always be measured<sup>2</sup>.

In addition, the [TMRP](#) Core Outcome Set subgroup are trying to identify the source of all final core outcomes in terms of where the outcomes were suggested from.

<sup>1</sup> Turk D, Dworkin R, Revicki D et al. (2018) Identifying important outcome domains for chronic pain clinical trials: an IMMPACT survey of people with pain. *Pain* 137:276-85

<sup>2</sup> van 't Hooft J, Duffy JMN, Daly M et al. (2016) A Core Outcome Set for evaluation of interventions to prevent preterm birth. *Obstetrics & Gynecology* 127(1):49-58

**Question 11- Might core outcome sets may vary with severity of conditions?**

**Answer** - Yes, for example a core outcome set for localised prostate cancer would be different from a core outcome set for advanced prostate cancer.

**Question 13 - Is there anything else either Maureen or John would add to what they have learned?**

**Answer 13a** - John (patient participant in a COS study). One of the biggest surprises of the consensus meeting was the different perspectives of the same thing. I look at diabetes as what it's

doing to me and it was really, really interesting and very valuable to see that other people had a different viewpoint on the outcomes. On a personal level I also felt really empowered by the experience of taking part in the study, I became part of the solution rather than just 'someone living with Diabetes'.

**Answer 13b** - Maureen (patient research partner in a COS study). It was all about the right preparation for the families who participated so that they were able to do so meaningfully. My first experience of a Delphi study was when it just dropped into my email, I had no training, I didn't really understand what it was doing and it wasn't a very positive experience so I think a lot of it, when you want to involve patients, families and caregivers, a lot of thought has to go into exactly how you are going to do that. It is trial and error, you're not expected to do it perfectly, but there's a lot of resources out there and there's a lot of people to speak to. You have to really do it in a purposeful way so that those people can participate and that includes, if it's an in person meeting, preparing the other people who are sitting around the table. We started off our consensus meeting by explaining who was there, explaining exactly what the patient partners had done and how they had been involved in the project, because we may think that the researchers and other stakeholders know that but we can't take that for granted. So I think that what I learnt most was that preparation is really key and building relationships with the families that you are engaging with is key to everything.

**Question 14: What is the frequency to update or add/review a specific outcome set? And what will be the most appropriate mechanism (to trigger it)?**

**Answer:** This will vary according to how research in that specific health condition is progressing. Not too often though as otherwise it defeats the object of a COS. We want people to monitor uptake of a COS in order to see whether particular outcomes are just not being measured, and to look into the reasons for that, to inform an update

**Question 15: Comment rather than question... I've been involved in developing NICE guidance. Much research was essentially lost to the work of the GDC because we couldn't compare like with like.**

**Answer:** Please see the link on [COMET's COS endorsement page](#) – the National Institute for Clinical Excellence (NICE) in the UK are recommending GDCs consider COS when setting scope. We hope this may influence trialists in terms of what they then measure in their research.