Research ethics considerations for core outcome set studies with patients

This document aims to provide clarification regarding some questions that have arisen about the role of patients in core outcome set studies (COS) and ethics approval requirements.

First it is helpful to note that patients can have two different roles in COS studies:

- **Patient participants** - in this role patients input by providing data on their opinions about outcomes.
- **Patient research partners** – in this role patients input as advisors or co-investigators helping the team to plan and deliver a COS study.

For both roles we provide clarification on ethical considerations.

Patient participants

Like all research studies, COS studies can present numerous ethical issues for patient participants, for example:

- discussing which outcomes a patient feels are important can sometimes bring underlying distress to the surface;
- being party to discussions about the potential future impact of a condition may cause patients anxiety;
- in consensus meetings patients might feel unable to voice their own concerns if their treating clinician is also present;
- in meetings there might be conflict between patients or between patients and professionals that may cause upset.

Some confusion has arisen regarding whether COS development is research or consultation and whether ethical approval is required for the seeking the opinions of patients on outcomes. In the UK, the Health Research Authority (HRA) has advised that if COS development aims to create generalizable knowledge, it is research and therefore requires ethical approval. The precise ethical approvals needed vary from country to country and appropriate advice should always be sought from the relevant authorities in your country. The HRA has also advised that where a study involves patient participants identified through the National Health Service, review by an HRA ethics committee will be required. In many cases, COS studies will be eligible for proportionate review. However, there are situations where a full review may be required, such as for particularly sensitive topics.

Some research teams have opted to use patient organisations to access patient participants. In the UK this process still requires institutional ethical approval (e.g. by a University ethics committee or institutional review board). However, researchers should note that patients in contact with patient organisations are self-selected and this may affect the generalizability of your findings.

Patient research partners

As noted above, patient research partners help the team to plan and deliver a COS study. In the UK ethical approval is not required to seek input from patients on the planning and design of studies. However, again the regulations vary from country to country and appropriate advice should always be sought from the relevant authorities in your country.

Patient research partners can input to COS studies in many different ways (please see Young & Bagley, 2016[1] for further details). In particular, patient research partners can offer valuable advice on the ethical issues relevant to your COS study. This can help your team to minimise any risk to patients from

participation and facilitate the ethics approval process.

If patient research partners have a hands-on role in collecting data for a study, there are other issues that need attention. Involvement as co-researcher (e.g. as a moderator of a focus group or interviewer) may require formal research and ethics training. In some circumstances a contract of employment may also be required, together with health and police checks. For further information see the joint statement by the Health Research Authority and INVOLVE[2] (England).

As in any research study, patient research partners involved in COS studies need to be supported in their roles, including providing them with understandable information about the aims and process of COS development and offering opportunities for patient research partners to discuss their contributions and develop their roles. Organisations such as INVOLVE[3] in the UK provide further general information about supporting patient partners in research studies. The steps taken to support patient research partners should be outlined in your COS study protocol.

References and links

1) Young B., & Bagley H. (2016) Including patients in core outcome set development: issues to consider based on three workshops with around 100 international delegates. *Research Involvement and Engagement* 2:25

2) Health Research Authority & INVOLVE. Public involvement in research and research ethics committee review: http://www.invo.org.uk/wp-content/uploads/2016/05/HRA-INVOLVE-updated-statement-2016.pdf