Questions regarding planning the overall COS study design

Agreeing on the scope and setting of a COS study

When agreeing the scope and setting of the COS study, PRPs can collaborate with the research team to consider:

PRPs can help the research team consider:

- What should the scope of the COS be?
    - Which patients / members of the public should this COS be for - for example, only patients with a particular type of epilepsy, or all patients with any type of epilepsy.
    - What type of treatment / intervention the COS will be for - for example, only surgical treatment or only physiotherapy treatment for a slipped disc.
    - Whether patients / the public from particular countries are important to involve and why - for example in some countries particular diseases are more common.

Writing a COS study research proposal

The research proposal forms the basis of the research protocol, so the research team should think through key aspects of the COS study at this point. When developing the research proposal, PRPs can collaborate with the research team to consider:

- How a list of outcomes will be generated for the COS study
    - What methods should we use to ensure the long list of outcomes includes patient important outcomes?
- How consensus will be sought:
    - What methods should we use to gain consensus about the core outcomes with patients as key participants?
    - Will the methods need adapting for the patient population(s) to be targeted? For example, if children and young people are to participate or if the condition that the COS is being developed for means additional support is needed to facilitate people's participation?
- Who the study participants should be and how to recruit them:
    - Which approaches to recruiting patients should we use and why?
    - How can we ensure diversity in our study participants?
    - If this study is being conducted internationally what should we consider (note, some countries don't have patient organisations)
- Maintaining patient participant interest over time:
    - What retention challenges might we face in this study (e.g. asking patients to complete a similar survey on more than one occasion, or inviting survey participants to a final consensus meeting)?
    - How might these challenges be addressed?
- Patient and public involvement (PPI) in the study:
    - How best can patients be involved in the design, delivery and dissemination of this COS study if funded?
    - If plans have already been made for PPI are they achievable, inclusive and appropriate?

    - Has appropriate support and compensation been factored in to the proposal and do the plans take into account any differences in different countries – for example, any specific consideration of making payments for PPI?
- Study oversight
    - Are patients appropriately represented on the oversight committee?
    - How might the oversight committee membership be more inclusive?

PRPs can also help you develop a plain language summary of your proposal and provide feedback on the general readability of your research application and proposal. This is important as patients and the public from the funding organisation are usually involved in funding panels that review research proposals.

Developing a COS study research protocol

When developing the COS study research protocol, PRPs can collaborate with the research team to consider:

- The planned methods for your study
    - How can the methods be planned to best suit the needs of patient / public participants in your COS study? (e.g. will any physical needs related to the health condition have an impact on taking part, such as cognitive issues / pain when sitting for long periods, etc)
    - What ethical issues might there be and how might these be addressed?
- Participant information sheets and consent forms
    - How appropriate and understandable are your participant information sheets and consent forms?
    - How is the information presented in these resources – is it accessible for patients / the public?
    - What other information might someone find helpful in deciding whether to take part?
- The COS study recruitment strategy
    - What should our key recruitment message be for potential patient participants?
    - How can we best recruit patients to the COS study?
    - If the study is international how can we recruit in countries without patient organisations?
    - How should we address the need for translation of the resources into different languages?
    - (if using emailed / mailed invitations)
        - What should our research invitations say and what email header should be used?
        - How should the invitations be designed to be accessible and engaging to potential participants?
    - (If using social media) How can we best access patients through social media (which channels and what times) and what key messages should we give?
    - (If in-person approaches are to be used) who should invite patients and what should they say about the study?
    - (If developing a website) How should our COS website be designed so that it is accessible and easy to navigate?
- COS study retention

    - What information should be given to participants between rounds of the Delphi to ensure that they know what to expect with further survey rounds?
    - What information should be given in further survey rounds to ensure the participants understand the difference between previous rounds and the current rounds and what they are required to do?
    - How best can survey participants be encouraged to participate in any later consensus meetings?
- Results dissemination
    - What should we plan to do in terms of disseminating the results to patient participants?
    - What should we plan to do in terms of disseminating the results to the wider patient / public community?