



- COMET Initiative Patient and Public Involvement, Participation and Engagement

Five-year Strategy

January 2023

1. Background

1.1 - About the COMET Initiative

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (<http://www.comet-initiative.org/>) is an international initiative that brings together people interested in developing and applying agreed standardised sets of outcomes known as '[core outcome sets](#)' (COS). These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition. They are also suitable for use in clinical audit or research other than randomised trials. A COS does not imply that outcomes in a particular trial should be restricted to those in the relevant COS. Rather, there is an expectation that the core outcomes will be collected and reported, making it easier for the results of trials to be compared, contrasted and combined as appropriate while researchers continue to explore other outcomes. COS need to include outcomes that are most relevant to patients and the public, so it is vital that they are involved in the development of COS. COMET aims to:

- collate and encourage the development of relevant resources in COS (such as plain language summaries and relevant publications and guidance),
- facilitate the exchange of ideas and information and
- foster methodological research in COS development and uptake.

1.2 - The emergence of the COS community

Recent years have seen the emergence of a growing and vibrant COS community. By 2021 there had been 370 published COS studies (for 447 COS) and there were 368 ongoing COS studies. However, only around 20% of published COS studies have included low and middle income (LMIC) countries(1). Higher levels of patient and public participation have been reported in COS in LMICs compared to COS in High Income Countries (HICs) (LMICs 57%, HICs, 32%(1)). Whilst LMIC stakeholder participation is increasing, a better understanding is needed of the challenges of including patients and the public from diverse international communities and ways to overcome these challenges.

Whilst COS development has increased, a key challenge is ensuring COS are used once developed. Research suggests COS uptake is low(2), even five years after COS publication, potentially contributing to further research waste (research that fails to advance scientific understanding)

1.3 - How can patients and the public input into COS development

There are two main ways patients and the public can input into COS development:

Patient and public involvement:

Patients and the public can help to design and oversee the COS development process as patient research partners. In the UK, this is called 'patient and public involvement, but in other countries, different terms are used, including 'patient and public engagement' and 'consumer involvement'.

Patient participation:

This is where patients and the public participate in the COS research study, providing their opinions on which outcomes are important to them. For example, they might be participants in an interview study to help the COS team understand which outcomes are important to patients and why. They can also contribute to consensus processes such as Delphi surveys and consensus meetings, where outcomes are scored/prioritised to agree on the core outcome set.

An animation explaining more about patient and public involvement in COS development can be found [here](#).

In addition to patients and the public being involved and participating in COS studies, they can also be informed about COS.

Note: When we refer to both involvement and participation at the same time we will use the term 'inclusion'

1.4 - Patient and public participation in COS and the importance of uptake

In 2014 COMET reported that only 16% of 198 COS studies had included patients and the public either as participants, research partners or both. Since 2014 there has been a dramatic increase in patient and public participation in COS studies, with searches of the COMET Database in November 2022 indicating patient and public participation in 44 % of published and 93% of ongoing COS studies. An increasing number of COS studies also describe involving patients and the public as partners in the development, design and delivery of COS(3). We can see that patient and public participation in COS work is becoming increasingly prominent.

COS need to be relevant to patients and the public internationally. However, as noted above there are challenges in conducting COS research globally, such as translation issues(4) and difficulties reaching or engaging patients and the public using traditional consensus approaches(1). Despite this, we see increasing numbers of COS studies striving to engage more international stakeholder groups(5).

Developing a COS is initially about agreeing which outcomes are so crucial (for a condition or intervention) that they should be measured in all trials in that area. Once these core outcomes have been agreed upon, further research is needed to determine how those outcomes are measured. Failing to agree how the core outcome sets should be measured can impact negatively on COS uptake(2).

As the number of COS grows it is important to promote their uptake to ensure that the continued development of COS does not lead to research waste through poor uptake and ensure that patients, health professionals and researchers benefit from the COS that have

been developed. Increasingly research funders, including some patient organisations, are [endorsing the use of COS](#).

1.5 How can patients and the public input into COS uptake?

Patients and the public who are public research partners (PRPs) can help promote COS uptake. PRPs involved in patient organisations or clinical trials can raise awareness of an existing COS. The [COMET COS database](#) can be used to search for existing COS.

1.6 - About the PoPPIE Working Group

The COMET People and Patient Participation, Involvement and Engagement (PoPPIE) working group's role is to lead and oversee the public participation, involvement and engagement work of the COMET Initiative, as set out in this strategy.

COMET established the COMET People and Public Participation, Involvement and Engagement (PoPPIE) Working Group in 2015. Since this time PoPPIE members have developed numerous resources and undertaken several events and activities designed to:

- Explain what COS are, why they are needed and how they are developed
- Promote the need for patient and public input into COS development
- Raise awareness of the work of the COMET Initiative with patient/public and Patient and Public Involvement (PPI) organisations
- Provide a central hub of resources for COS developers who are including patients and the public in their works,
- Contribute to COMET's broader areas of work such as the standards for COS development(6).
- Embed patient and public involvement in the activities of the COMET Initiative

1.7 - COMET PoPPIE Strategy Meetings

On the 19th January and the 9th March 2022, COMET's PoPPIE Working Group hosted its Strategy Development Meetings to revise the previously developed (2014) COMET PPI

strategy. The names of members of the COMET PoPPIE Working Group who attended the meetings can be found [here](#).

2. Vision and objectives

2.1 - Our vision

Our overall goal is to ensure the involvement and participation of patients, parents, carers and members of the public internationally in COS development (both ‘what’ to measure and ‘how’ to measure) and to promote COS uptake amongst relevant patient and public communities once COS are developed.

2.2 - Our objectives

1. Raise awareness of what COS are, the importance of COS uptake and the work of the COMET Initiative
2. Ensure PoPPIE’s resources meet the information needs of COS developers, patients and the public, and PRPs, in relation to both the ‘what’ and ‘how’ aspects of COS development
3. Promote diversity and accessibility in COS development and embed public involvement in the activities of the COMET Initiative
4. Work with others to further research into how to optimise patient participation, involvement and engagement in COS development.

3. How will this strategy be achieved?

The COMET PoPPIE Working Group ([Terms of Reference and Membership](#)) will work on behalf of the COMET Initiative to produce a plan setting out how we will achieve the objectives in this strategy.

4. Acknowledgments

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5. References

1. Karumbi J, Gorst SL, Gathara D, Gargon E, Young B, Williamson PR. Inclusion of participants from low-income and middle-income countries in core outcome sets development: a systematic review. *BMJ open*. 2021;11(10):e049981.
2. Williason PR, Barrington H, Blazeby JM, Clarke M, Gargon E, Gorst S, Saldanha IJ & Tunis S. Review finds core outcome set uptake in new studies and systematic reviews needs improvement. *Journal of Clinical Epidemiology*. 2022; Vol.150, p.154-164
3. Barrington H, Young B, Williamson PR. Patient participation in Delphi surveys to develop core outcome sets: systematic review. *BMJ open*. 2021;11(9):e051066.
4. Alkhaffaf B, Blazeby JM, Metryka A, Glennly A-M, Adeyeye A, Costa PM, et al. Methods for conducting international Delphi surveys to optimise global participation in core outcome set development: a case study in gastric cancer informed by a comprehensive literature review. *Trials*. 2021;22(1):410.
5. Biggane AM, Brading L, Ravaud P, Young B, Williamson PR. Survey indicated that core outcome set development is increasingly including patients, being conducted internationally and using Delphi surveys. *Trials*. 2018;19(1):1-6.
6. Kirkham JJ, Davis K, Altman DG, Blazeby JM, Mike M, S T, et al. Core Outcome Set-STAndards for Development: The COS-STAD recommendations. *PLoS Medicine*. 2017;14(11):e1002447-e.