# COMET Initiative Public Involvement Strategy

## July 2014

## About the COMET Initiative*

The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (http://www.comet-initiative.org/) is an international initiative to bring together people interested in the development and application of agreed standardised sets of outcomes, known as 'core outcome sets'. These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition, and are also suitable for use in clinical audit or research other than randomised trials. The existence or use of a core outcome set does not imply that outcomes in a particular trial should be restricted to those in the relevant core outcome set. 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 as well. COMET aims to collate and stimulate relevant resources, both applied and methodological, to facilitate exchange of ideas and information, and to foster methodological research in this area.

Core outcome sets need to include those outcomes that are most relevant to patients and carers, so it is vital that patients and carers are involved in their development. There are examples of where involving patients in the process identified an outcome that was important to them as a group but which might have been overlooked if the outcome set was developed by practitioners on their own. COMET recognises the expertise and crucial contribution of patients and carers in developing relevant core outcome sets. COMET aims to develop resources and stimulate research to facilitate involving patients and the public in the development of core outcomes set.

(* For a Plain language summary of what core outcome sets are and what the COMET Initiative is see http://www.comet-initiative.org/resources/PlainLanguageSummary)

## Current PPI involvement in core outcome sets

In June 2014, COMET published a systematic review of core outcome set work up to 2013 (click the following link to read this study). Only 16% of 198 studies up to the point of the review had involved the public as participants in their studies. In terms of involving patients in the design of COS studies, only 2 out of 198 studies described involving patients.

This situation is changing. There are 46 ongoing studies listed in the COMET database. Of these 46 studies, 40 have PPI stakeholders described (87%). So we can see that public involvement in core outcome set development is becoming increasingly prominent and therefore the focus should also include encouraging researchers to look at the quality of patient involvement in core outcome set development

## 'COMET - Involving People' Meeting

On the 27th March 2014 COMET hosted a meeting 'COMET – Involving People'. This was a collaborative meeting between UK-based public involvement organisations, core outcome set developers and the COMET Initiative. The aims of the meeting were to:

- Raise awareness amongst attending public involvement organisations about the work of COMET
- Identify resources that are relevant to facilitate public involvement in the work of COMET
- Discuss a strategy for engaging patient organisations in the work of COMET.

This interactive event involved a substantial amount of group work in order for COMET to learn from the experiences of those attending the meeting. The three group work sessions focussed on the following questions:

- What are the challenges of involving patients and the public in core outcome set development?
- What should COMET's strategy be to engage patient organisations in its work?
- What resources/research should be developed to facilitate the involvement of patients in core outcome set work?

The initial public involvement strategy for COMET was developed as a direct result of the contributions at this event and the learning that COMET gained from the expertise of the delegates who attended.

Additional contributions to the action plan have been provided by core outcome set developers at a meeting in Bristol in June 2014, which involved COS developers at various stages in the process of undertaking COS studies.

## Our Public Involvement vision

Our overall public involvement goal is to facilitate the involvement of patients, parents, carers and members of the public as key stakeholders in the development of core outcome sets.

## Our Public Involvement objectives

1. To raise the awareness of the need to develop core outcome sets and the work of the COMET Initiative amongst Public Involvement organisations
2. To raise the awareness of the need to develop core outcome sets and the work of the COMET Initiative amongst Patient organisations e.g. patient charities/support groups
3. To be a central information hub with guidance and resources to facilitate the involvement of patients in COS development
4. To produce resources for COS developers to assist them in planning for public involvement in both the design and conduct of core outcome set studies
5. To produce resources for patients interested in finding out more about core outcome sets and the COMET Initiative
6. To work with other groups to identify opportunities for developing core outcome sets with public involvement
7. To embed public involvement in the activities of the COMET Initiative
8. To collate examples of the impact of public involvement on core outcome sets
9. To work with others to further research into how to optimise patient involvement in COS development.

## How will this initial strategy be further developed?

In order to achieve this initial strategy, we are establishing a COMET Public Involvement working group. Terms of Reference for, and membership of this group will be available on the COMET website in due course. Appendix 1 includes a draft Action Plan.

## Acknowledgments

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## Appendix 1 Draft Action Plan

| Objective | Task | Timeframe |
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| **1.** To raise Public Involvement (PPI) organisation awareness of the need to develop core outcome sets and the work of COMET Initiative | • Present information about the work of the COMET initiative at INVOLVE conferences and produce an article for the INVOLVE newsletter.<br>• Continue to ensure links to information about the COMET initiative are available on any international PPI websites.<br>• Develop a series of slides to use to present at any PPI meetings / events about core outcome sets and the work of the COMET Initiative.<br>• Attend the NICE 'Patients Involved in NICE' group and give a presentation about core outcome sets and the COMET initiative.<br>• Develop links with EUPATI, INVOLVE and the Building Research Partnership to explore the possibility of incorporating the COMET initiative slides as part of their PPI educational activities.<br>• Provide resources to train public reviewers of research study applications to refer to the COMET database | |
| **2. To raise patient organisation awareness of the need to develop core outcome sets and the work of COMET Initiative** | • Develop links with umbrella patient organisations nationally and internationally to cascade down information about the COMET initiative.<br>• Develop plans / apply for funding to host another event similar (but smaller scale)to the Involving People event specifically for umbrella | |

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|  | patient organisations. |  |
| **3. To be a central information hub to facilitate public involvement in COS development;** | With the support of PPI representatives and COS development advisers, produce guidance / resources for researchers on the public involvement aspects of COS development, including:<br>• Resources for researchers to use when approaching patient organisations for involvement in a COS study (with the involvement of patient organisations in the production of these resources).<br>• Guidance notes on involving patients in designing a core outcome set study<br>• Guidance on how to develop appropriate questions to elicit patient views (including links to guidance on plain English) and information about technologies to enable information to be provided to both professionals and the public in appropriate language<br>• Case studies of public involvement in core outcome set development including lessons learnt<br>• Guidance on how to plan a COS involving patients as research partners (planning the project)<br>• A signposting mechanism on the COMET website to direct researchers to guidance about public involvement in research. Seek INVOLVE support in identifying relevant areas of their resources. Identify any gaps that exist in these existing resources in relation to the development of core outcome sets. |  |

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| | • A broad discussion document on the ethical aspects of involving patients / carers as:<br>○ Research partners in COS study design and<br>○ stakeholders in core outcome set studies based (including the issue of offering incentives)<br>• A template for the reporting structure of PPI aspects of a COS study.<br>• Examples of materials used in engaging the public in other COS studies, including invitations to take part, survey designs, survey voting forms / mechanisms etc. These will be annotated with information about the pros and cons of the resources.<br>• A bank of glossaries – examples of glossaries used in other studies / a general glossary of terms document.<br>• A 'Success Stories' space on the web site – examples of how COS has improved consistency across trials / how COS make a difference (as a way of promoting the utility of the end product so that researchers could explain to patients the impact of patient involvement into COS).<br>• Methodology papers public involvement references section on the website<br>• Repository of plain language summaries<br>• Guidance / case studies about how to access patients, including how to involve people from hard to reach communities, how to involve patients when no patient organisation exists, and the use of social | |

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|  | media in engagement (considerations etc)<br>• Guidance / case studies on how to facilitate consensus meetings involving patients, including links to any useful tools to do so Also to include information on how to prepare public contributors for taking part in consensus meetings<br>• Tips for good public engagement<br>• Produce plain language summaries of consensus methods.<br>• Collate existing plain language summaries on consensus methodologies.<br>• Examples of pre plain language summary information sheets (briefer more condition focussed information)<br>• FAQ section<br>• Examples of studies that have fed back the study result to study participants and examples of where study results have been published by patient organisations<br>• Information for Pharma on the importance of COS and public involvement in their development<br>• A video / cartoon around understanding outcomes. |  |
| **4. To produce resources for COS developers to assist them in planning for public involvement in** | • Develop signposting to relevant flagship patient involvement sites for guidance on patient and public involvement into the design of core outcome sets |  |

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| **both the design and conduct of core outcome set studies** | • Collate examples of information and resources used to involve patients in designing a core outcome set as research partners | |
| **5. To produce resources for members of the public interested in finding out more about core outcome sets, the COMET Initiative and consensus building** | • Adjust the plain language summary in line with comments and recommendations from the COMET Involving People event.<br>• Develop plans to offer an overview of core outcome sets and the work of COMET in other formats eg. audio / video.<br>• Collate personal testimonies / podcasts from patients involved in core outcome set projects – identify mechanisms /resources/funding sources for developing these. | |
| **6. To work with other groups to identify opportunities for developing and adopting core outcome sets** | • Through the COMET Steering Group, COMET will lobby for INVOLVE to endorse the work of the COMET Initiative and to have, as part of PPI training to undertake reviews, information about COS and the COMET database. | |
| **7. To embed Public Involvement in the activities of the COMET Initiative.** | • Develop a remit document for PPI representatives on COMET groups and set up a selection process. Develop induction materials for the role and a mechanism for evaluating involvement. | |
| **8.To collate examples of the impact of public involvement on core** | • Through the qualitative interviews collate any examples of the impact of public involvement in core outcome sets<br>• Request information from COS developers on any impact of public | |

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| **outcome sets** | involvement on core outcome sets<br>• Develop a list of examples of the impact of public involvement in core outcomes sets |  |
| **9.To work with others to further research into how to optimise public involvement in core outcome set development'** | • To identify and publicise research funding opportunities for methodological studies addressing public involvement in core outcome set development<br>• To undertake a consensus exercise to develop a priority list of research topics exploring how to optimise public involvement in core outcome sets<br>• To encourage researchers undertaking core outcome set studies to consider incorporating methodological research that examines the issue of stakeholder involvement in particular public involvement in core outcome sets.<br>• To provide advice to research teams developing / undertaking methodological research into optimising public involvement in core outcome set development |  |