The Red Hat Group: an initiative to promote broader uptake of core outcome sets through the healthcare research ecosystem

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Background

- Core outcome sets (COS) for trials are the minimum set of outcomes that should be measured and reported in all clinical trials in a specific condition. COS can be developed for research, routine care, or both. This allows research to be compared and combined as appropriate, and would ensure that all studies provide usable information.
- In the decade leading up to 2019, uptake of the rheumatoid arthritis COS in clinical trials was maintained at just over 80% (1). Those commercially funded were more likely to plan to measure the outcomes, probably influenced by EMA and FDA endorsement of the COS. Uptake is much lower in other clinical areas where assessed, however, and action is needed.
- The landscape surrounding COS has developed significantly over the last five years. Recognition of the potential influence and levers that may incentivise broader uptake of COS across the healthcare research ecosystem is increasing.

Red Hat Group

The Red Hat Group (RHG) was formed at the COMET VII meeting in Amsterdam in 2018, and comprises several initiatives related to improving choice of outcomes in health research – COMET, OMERACT, CS-COUSIN, GRADE, CMTP, COSMIN, CDISC and SONG.

Core Outcome Set-STAndards for Development (COS-STAD)

recommendations were established to:

- improve the methodological approach for developing COS,
- and help users assess whether a COS has been developed using a reasonable approach.

The COS-STAD minimum standards COS development identify patients, health professionals and those who should use the COS in their research as key stakeholder groups to include (2).

In the context of the COS-STAD Delphi exercise, consensus was not quite reached that 'users of the research that should have used the COS' must be included (2).

Experience of engaging users such bodies, regulatory clinical organisations, and guideline development groups in COS development has been limited to date. The Red Hat Group aims to explore necessary and sufficient conditions for broad endorsement and uptake of COS by these groups.

Outcome Measures in Rheumatology (OMERACT) OMERACT is an independent initiative of international health professionals & patient research partners interested in outcome measures & measurement methodology, especially in rheumatology.



Standardised Outcomes in Nephrology (SONG) Initiative SONG aims to establish and implement core outcomes across the spectrum of chronic kidney disease.



MacGRADE Centre, **McMaster University**

Centre | McMaster University The MacGRADE Centre['] aims to develop & test methodological innovations to improve rigour when rating the certainty of the evidence & developing guideline recommendations.

Aims

The initial objective is to work together on a project to share knowledge and understanding of mechanisms to promote uptake of COS in comparative effectiveness research.

Core Outcomes in Effectiveness Trials (COMET) Initiative

COMET aims to collate COS, stimulate relevant resources, & foster methodology research in the area of COS development.



RHG aims to:

(1) to identify work of mutual interest which would benefit from combined efforts;

(2) to develop joint activities to strengthen the field, and reduce unnecessary duplication of effort;

(3) to discuss common challenges with process and methods of COS development; to promote research in areas of uncertainty; to share solutions and best practices;

(4) to discuss ways to promote uptake of COS and work together to raise awareness;

(5) to promote discussion and joint work around the alignment of outcomes for research and clinical practice.

cdisc

Clinical Data Interchange Standards Consortium (CDISC)

CDISC aims to develop & advance data standards of the highest quality to transform incompatible formats, inconsistent methodologies, and diverse perspectives into a powerful framework for generating clinical research data that is accessible, interoperable, & reusable.

Center for Medical Technology Policy (CMTP)

CMTP aims to make healthcare more effective & affordable by improving the quality, relevance, & efficiency of clinical research. A key aspect is to engage all relevant stakeholders early in clinical research design for greater transparency on evidence needed by patients, providers, & payers/HTA.



Cochrane Skin Core OUtcome Set INitiative (CS-COUSIN) CS-COUSIN aims to support,



standardize & improve the development and implementation of core outcomes sets in the clinical field of dermatology.



COnsensus-based Standards for the selection of health **Measurement Instruments** (COSMIN)

COSMIN aims to improve the selection of outcome measurement instruments by developing methodology & practical tools for selecting the most suitable instrument.

Methods

- Survey of COS developers about their implementation strategies.
- All groups are identifying their spheres of influence to identify a strategy for improving uptake for two specific COS:
 - osteoarthritis and type II diabetes.
- Plenary panel discussion at OMERACT 2020.

References

GRADE

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