Proceedings of the 5th Meeting of the Core Outcome Measures in Effectiveness Trials (COMET) Initiative

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presented findings from a survey of outcomes in Cochrane Reviews, showing the wide variation in outcomes and the lack of COS, at least up to 2013. Holger Schünemann (McMaster University) closed the plenary session by providing an overview of the GRADE evidence to decision frameworks.

Following a break, the participants headed off for one of three COMET workshops. Paula Williamson led the first of these, which focused on the methods for developing what to measure in COS. The workshop introduced methodological issues and considerations involved in developing COS. Workshop 2 was led by Mike Clarke and looked at how COS might be used for randomised trials and Cochrane Reviews. Bridget Young (University of Liverpool) led the third workshop providing an interactive opportunity for the participants to identify the challenges that researchers may encounter when planning to involve patients and carers in COS development.

COMET V allowed a wide variety of stakeholders with an interest in COS development to meet and share experiences, findings, and plans with others. It brought together key scientists and consumers responsible for developing and implementing COS. Patient involvement emerged as a major focus of the meeting with an emphasis on engaging the relevant stakeholders early in the process of COS development. Thoughts were offered for how COMET can evolve both in Canada and the rest of the world. Several questions were posed throughout the meeting, including: How can we ensure that COS are well developed in the first place? Is there a magic number of outcomes to be included in a COS and, if so, what is it? As COMET looks forward to COMET VI, it will seek to meet these challenges, guided by an International Advisory Group, which will include Peter Tugwell (University of Ottawa), one of the founders of OMERACT.

The slides from COMET V presentations can be viewed at: http://www.comet-initiative.org/events/FifthCometMeeting.

**ORAL PRESENTATIONS**

**01** A minimum core outcome set for clinical trials on non-minimal-invasive off- or on-pump cardiothoracic surgery
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Trials 2015, 16(Suppl 3):O1

**Background:** Cardiovascular disease (CVD) is a major contributor to the burden of disease and the number one cause of death worldwide. From 1990 until today, more people have died from coronary heart disease than from any other cause. CVD is regularly treated with minimal or non-minimal-invasive off- or on-pump cardiothoracic surgery and interventions related to the outcome of the surgical procedures are regularly evaluated in clinical trials, but heterogeneity in outcome reporting hinders comparison of interventions and limits the ability of research synthesis. This problem is encountered by core outcome sets (COS) that should be measured and reported – as a minimum – in all clinical trials for a specific clinical field.

**Method:** We are developing a COS for clinical trials measuring the efficacy and effectiveness of pre-, intra- or post-surgical interventions in non-minimal-invasive off- or on-pump cardiothoracic surgery and procedures related to the outcome of the surgical procedures are regularly evaluated in clinical trials, but heterogeneity in outcome reporting hinders comparison of interventions and limits the ability of research synthesis. This problem is encountered by core outcome sets (COS) that should be measured and reported – as a minimum – in all clinical trials for a specific clinical field.

**Results:** The eDelphi is currently being carried out. We will present identified core outcome domains at the COMET V Meeting.

**Conclusion:** The proposed COS aims to provide methodological guidance in future cardiothoracic surgical clinical trials. This does not imply that primary outcomes should always and exclusively be those of the COS. However, to assure the comparability of results across trials the outcomes included in this COS should be considered for inclusion besides measuring trial-specific clinical endpoints.

**02** Patient engagement – the PaCER model
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Trials 2015, 16(Suppl 3):O2

**Background:** Training citizens living with various health conditions to design and conduct health research, using adapted methods of qualitative inquiry, paves the way for new approaches. Patient and Community Engagement Researchers (PaCERs) collaborate with health professionals, policy makers and engage other patients in all phases of research from setting study questions, agendas, implementation, through to the uptake of results.

**Method:** With several studies now complete, this presentation will focus on strengths of patient-led research. The PaCER method of data collection and analysis engages patients in focus groups to define the scope and research questions (Set), followed by various data collection activities such as focus groups, questionnaires, observation, narrative interviewing (Collect), and a final (Reflect) focus group. Research protocols are negotiated in collaboration with academic researchers, ethics panels, funders and PaCER teams.

**Results:** PaCERs have enhanced the research community in tangible ways. Individuals involved in the experience have developed both the self-confidence and competence to be more meaningfully engaged in research outcomes which impact care protocols and the negotiation of healthcare policy. Healthcare professionals have new tools to obtain credible data that are relevant to patients. Based on examples from several recent PaCER studies, this presentation will demonstrate that patients often reveal formerly unknown commentary on how they experience current best practices and entirely refreshing views of optimal treatment, care and outcomes from the patient as consumer perspective.

**Conclusion:** The patient engagement research approach will improve the results of patient experience and outcome analysis, in any clinical research area. Adding the active voice, and research minds of patients can enrich the patient engagement process in outcome research.

**03** Public engagement in outcomes development - three degrees of separation
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Trials 2015, 16(Suppl 3):O3

**Background:** This presentation will focus on a UK Cochrane funded project that explored different ways of engaging patients, the public and health practitioners in the development of outcomes for systematic reviews. It is called ‘Outcomes Most Important for Patients, Public and Practitioners (OMIPPP).’

**Method:** Working with three Cochrane Review Groups (CRG): Airways, Ear Nose and Throat (ENT) and Pregnancy and Childbirth we focussed on outcomes for reviews in Asthma, Rhinosinusitis and Breastfeeding respectively. For each group we used a different method to engage; for asthma we facilitated a full day workshop. Working in partnership with Asthma UK, we prepared for this by gathering perspectives of asthma via a Facebook survey, and reviewing existing core outcome sets. Working in partnership with evidENT we gathered perspectives in rhinosinusitis using an online survey and experimented with social media as a way of reaching out beyond their networks as there are no relevant patient groups. We compared survey findings with existing outcomes used for reviews of chronic sinusitis. For breastfeeding we worked with the National Childbirth Trust and the Breastfeeding Network to review an existing online collection of experiences of breastfeeding called Healthtalk (http://www.healthtalk.org).
Healthtalk researchers reanalysed the original data for clues to outcomes. These were shared, discussed and compared with existing outcomes used in systematic reviews of breastfeeding interventions.

**Results:** At the time of writing this abstract the project is not yet complete, however early results will be discussed. We are interested in the following aspects of evaluation: how relevant was the gathered data for systematic review outcomes? What were the cost and resource implications of each method? From a review group perspective how feasible are these methods? Has the project extended the reach of CRGs with interested public/patient and practitioner groups? How does our data compare with other outcomes exercises e.g. COMET?

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**POSTER PRESENTATIONS**

**P1**
Assessment of main adverse drug reactions in systematic reviews and clinical trials of heparins for surgery prophylaxis
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Trials 2015, 16(Suppl 3):P1

**Background:** In September 2012, we published a Cochrane systematic review assessing the risk of heparin-induced thrombocytopenia (HIT) in postoperative patients. Together with haemorrhagic events, HIT is a main adverse reaction of heparins and its most important consequence is a paradoxical increase in the risk of thromboembolic complications.

**Method:** We evaluated the report of HIT in Cochrane reviews of unfractionated heparin (UFH) or low molecular weight heparins (LMWH) for thromboprophylaxis after any type of surgery from the 2013 to 2015, period after the publication of a Cochrane review focused on the frequency of HIT in surgical settings. Data extraction aimed to describe how often and accurately HIT was addressed as a specific outcome (primary or secondary) with a precise definition, and how complete was the report of the included clinical trials regarding HIT.

**Results:** Four reviews were identified, each one relating to different clinical settings: cancer patients undergoing surgery (n=1), retinal reattachment surgery (n=1), microvascular surgery for digital replantation (n=1), and major amputation of lower extremity (n=1). Only one review described HIT as secondary outcome and none of the reviews indicated the accepted definition of HIT when outlining the outcomes of interest. A total of 22 clinical trials were included in the reviews, comprising a total of 14,120 patients, but no report of HIT was described.

**Conclusion:** Systematic reviewers need to be aware of special concepts and definitions in order to collate quality and accurate data not just related to the efficacy of the drug interventions but also in relation of its safety. Considering the relevance, bleeding and HIT should be regarded as core outcomes for the assessment of the safety of heparins. However, the complex definition and testing requirements for the diagnosis of HIT may determine significant bias in the detection and reporting of this adverse drug reaction.

**P2**
TORCH: Toronto Outcome Research in Child Health - enhancing evidence based outcomes selection in pediatric research
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Trials 2015, 16(Suppl 3):P2

**Background:** Children’s responses to medical treatments differ significantly from adults. Appropriately selecting and measuring child and family relevant outcomes when designing pediatric clinical trials is important for decision making with regards to the health of the child. However, outcomes used to measure an intervention’s effectiveness in current pediatric clinical trials often lack child and family relevance, are heterogeneous across and within child health ages and diseases, and are not adequately measured with validated instruments. Furthermore, involvement of patients (children) and their proxies (usually parents) in outcomes selection is minimal. Inconsistent use of outcomes and outcomes measurement in pediatric clinical trials impairs the synthesis of evidence in systematic reviews and leads to outcome reporting bias. This high variability in outcome selection and measurement has led to a situation where child health decisions on treatment of children lack the appropriate underpinning evidence, and a subsequent inability to reach a consensus on the effectiveness and safety of a treatment. Recently, outcome selection initiatives in the general population such as OMERACT and COMET advocate homogeneity of methodology for outcome selection and measurement in trials.

**Method:** Toronto Outcome Research in Child Health (TORCH) is an exciting new collaborative initiative that develops and employs existing and new evidence-based methods for improving outcomes selection and measurement in cohort studies and trials in children.

**Results and discussion:** The TORCH platform raises awareness on the importance of meaningful outcomes selection and measurement in children; provides methodology to select measure and report truthful, discriminative and feasible outcomes in child health research; and supports engagement with research ethics boards, funders, journal editors and regulators to critically appraise outcomes selection, measurement and reporting in any child health research. The new TORCH platform will facilitate the translation of knowledge from the literature to bedside care, thereby improving child health outcomes while reducing the burden on the healthcare system.

**P3**
‘Getting back to normal’: using patients’ lived experience to inform a core outcome set for cardiac arrest clinical trials
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Background: A recent review of outcome reporting in out of hospital cardiac arrest (OHCA) clinical trials detailed a lack of transparency and heterogeneity, highlighting the need to establish a core outcome set (COS) (Whitehead et al., 2015). Moreover, the review highlighted the dominance of outcomes which focused on the pathophysiological manifestations of the event, clinicians’ perspectives, with an absence of outcomes which sought to explore the patients’ perspective. To ensure the development of a COS with relevance and meaning to all stakeholders - patients, clinicians and researchers, we sought to explore the views of patients and their partners to improve our understanding of the outcomes that really matter.

Methods: Semi-structured interviews were conducted with OHCA patients and, where possible their partners separately to gain a better understanding of the patients’ experience. Participants were recruited from a large NHS trust in the West Midlands, UK. Inclusion criteria included aged >18 years, cognitively able, and not critically ill. An interpretative phenomenological analysis was adopted.

Results: A convenience sample of eight patients (62.8 years (SD 13.6); range 41-79; n=5 male (62.5%) and three of their partners were interviewed, between 3 and 12 months post-arrest. At the time of interviews 2 had returned to work, 1 was planning a phased return to work, 4 were previously retired and 1 was previously unemployed. Analysis highlighted an overarching theme of “disruption to normality” with patients expressing a strong desire to get back to normal. The superordinate themes which contribute to this disruption include survival, physical function, emotional well-being, social well-being and participation and the impact on others.

Conclusions: This study details an exploration of the lived experience of the survivors of cardiac arrest and their partners. It provides clear, patient-derived guidance for the health outcomes that matter to patients and which should be considered for COS inclusion.

P5
Evaluation of measurement properties of pediatric acute diarrheal severity scoring systems

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Objectives: In this systematic review, we evaluated the measurement properties of ten commonly used instruments to assess the severity of acute diarrhea in children. We included all measurement properties in the included studies and the results of measurement property evaluations were appraised using checklists from the COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) group.

Methods: Medline, EMBase and the Cochrane library were searched using a highly sensitive search filter developed by Terwee et al. to identify studies that evaluated measurement properties. This search filter was combined with the names of ten pre-identified scales of pediatric diarrhea severity. Reference lists from included articles and the original publications for the ten diarrhea scales were also reviewed. Eligibility criteria were: 1) ability to develop or evaluate the measurement properties – i.e. content validity, construct validity, reliability or responsiveness – of a measurement instrument; 2) ability to measure severity of diarrhea/gastroenteritis; and 3) ability of the scale to be developed or adapted for the pediatric population (0-18 y/o). The methodological quality of the included studies and the results of measurement property evaluations were appraised using checklists from the COSMIN group.

Results: The search yielded 98 potentially relevant articles, of which only 2 articles met inclusion criteria. Studies that did not evaluate measurement properties of the identified scales or did not measure pediatric diarrhea were excluded. Both included studies evaluated the measurement properties of the “Modified Vesikari score” (MVS). Assessment of methodological quality determined that both studies were of ‘poor’ quality in most properties except for hypothesis testing, which was rated as ‘good’. MVS was rated as positive for face and construct validity and indeterminate for internal consistency and interpretability.

Conclusion: Despite their wide use, we found a disturbing lack of evidence evaluating validity and reliability of the most commonly used pediatric diarrhea severity scales. Further research with sound methodology is strongly recommended to properly evaluate the measurement properties of these scales. Moreover, to avoid heterogeneity, we encourage researchers to develop scales that measure outcomes identified in a newly developed core outcome set by the COMMENT group for clinical trials in acute diarrhea.

Acknowledgement: 5V receives salary support as an AHSc Health Scholar. We would like to thank Dr. Susanne K. Jones for her assistance with the database search and Dr. Caroline Terwee for her guidance with the application of COSMIN criteria.

P6
Is reviewing trial protocols on clinicaltrials.gov a feasible method of compiling a long-list for a core outcome set?

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Conclusion: A consensus on core outcome set for reporting for OAPS, involving clinicians across various subspecialties (rheumatology, obstetrics, maternal-fetal medicine, fertility and haematologists) and the patients is essential for studying the effectiveness of various treatment modalities.
Choosing important health outcomes for comparative effectiveness research: an updated review and user survey

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Trials 2015, 16(Suppl 3):P8

Background: A COS represents an agreed minimum set of outcomes that should be measured and reported in all trials of a specific condition. The COMET (Core Outcome Measures in Effectiveness Trials) initiative aims to collate and stimulate the development and application of COS, by including data on relevant studies within a publically available internet-based resource. In recent years, there has been an interest in increasing the development of COS. Therefore, this study aimed to provide an update of a previous review, and examine the quality of development of COS. A further aim was to understand the reasons why individuals are searching the COMET database.

Methods: A multi-faceted search strategy was followed, in order to identify studies that sought to determine which outcomes/domains to measure in clinical trials of a specific condition. Additionally, a pop up survey was added to the COMET website, to ascertain why people were searching the COMET database.

Results: Thirty-two reports relating to 29 studies were eligible for inclusion in the review. There has been an improvement in the description of the scope of a COS and an increase in the proportion of studies using literature/systematic reviews and the Delphi technique. Clinical experts continue to be the most common group involved in developing COS, however patient and public involvement has increased. The pop-up survey revealed the most common reasons for visiting the COMET website to be thinking about developing a COS and planning a clinical trial.

Conclusions: This update demonstrates that recent studies appear to have adopted a more structured approach towards COS development and public representation has increased. However, there remains a need for developers to adequately describe details about the scope of COS, and for greater public engagement. The COMET database appears to be a useful resource for both COS developers and users of COS.

Development of a core set of outcomes in children with severe neuro-disability and feeding tube dependency: a systematic review

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Trials 2015, 16(Suppl 3):P9

Background/Aim: Children with severe neuro-disability are at increased risk of feeding problems resulting in approximately half of such children being undernourished with growth failure. While gastrostomy tube feeding in such patients has been shown to improve weight gain, there is uncertainty to its impact on survival, respiratory complications, parental and child quality of life, cost, and consequently leads to potentially avoidable variability in practice. The issue of lack of standardized
outcomes for this population could be addressed through the development of a standardized core outcome set (COS). We aim to develop an evidenced-based COS for children 0-18 years with severe neuro-disability and dependent gastrostomy.

Methods and Results: A systematic review was undertaken to identify all outcome measures used in studies on children with severe neuro-disability dependent on gastrostomy tube feeding. PRISMA guidelines were followed. MEDLINE, EMBASE and Cochrane Register databases were searched from their inception until March 2015. Studies included systematic reviews with/without meta-analyses, randomised controlled trials, and observational studies. After initial screening of titles and abstracts, disagreements on the eligibility of studies were resolved through discussion. Data were extracted on study characteristics, outcomes measured, designated primary and secondary outcome(s), method of measurement, and time points at which they were measured. A thematic content analysis was undertaken to map the outcomes against the OMERACT framework that included four pre-specified outcome “domains”: mortality, pathophysiological manifestations, patient reported outcomes and healthcare utilization. To date, 8725 titles and abstracts are screened. A total of 1460 studies were found eligible. Final results will be presented at the meeting.

Discussion: Outcomes identified through this systematic review will be used to help stakeholders reach consensus on a COS for research in children with severe neuro-disability and feeding tube dependency which could be used to enhance future research, knowledge synthesis and inform clinical practice.

P10

EBRNetwork – a call to action for evidence-based research
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Trials 2015, 16(Suppl 3):P10

Background: Use of earlier research is needed to provide the rationale for starting a study and a context in which to set the study results. Explicit use of earlier research, through the conduct of a systematic review, is also necessary for the design of an efficient and informative study. Decisions about design informed by systematic review include the selection of meaningful outcomes assessed in a way that enables synthesis across studies; this is especially needed in areas where core outcome sets do not yet exist. Yet research shows that there is inadequate and biased consideration of earlier research.

Methods: In Bergen, Norway, in December 2014, the Evidence-Based Research Network (EBRNetwork) was initiated to promote the efficient and explicit use of existing research when new research is planned.

Results: We will present the aims, structure and activities of the EBRNetwork. Current activities include using peer-reviewed publications and social media to inform and engage researchers, funders, editors and the public. We will present for consideration a preliminary version of the Bergen Statement on Evidence-Based Research.

Conclusion: The design of new studies, including the choice of outcomes, should be informed by prior research. The new EBRNetwork is an international collaboration that aims to ensure that no new studies are approved, funded or published without systematic review of existing evidence; and works towards more efficient production, updating and dissemination of systematic reviews. The Network issues a call for participation.

P11

Reducing drinking in concurrent problem alcohol and illicit drug users: an impact story
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Background: One out of three people who receive methadone in primary care drink in excess of the recommended limits. This poses significant risk to their health, especially to their liver; it complicates their care and increases risk of relapse.

Objective: To inform addiction treatment in primary care with respect to psychosocial interventions reducing drinking in concurrent problem alcohol and illicit drug users, by: exploring the experience of (and evidence for) psychosocial interventions, developing and evaluating a complex intervention to improve implementation. Evaluation of the intervention tested core feasibility and acceptability outcomes for patients and providers.

Methods: A Cochrane review found only four studies. Having inconclusive evidence, we interviewed 28 patients, 38 physicians and nurses. Patient interviews informed development of a national clinical practice guideline, as well as design and outcomes of the evaluation project. Feasibility outcome measures included recruitment, retention, completion and follow-up rates, as well as satisfaction with the intervention. Secondary outcome was proportion of patients with problem alcohol use at the follow up, as measured by Alcohol Use Disorders Identification Test.

Results: Information from the Cochrane review and the qualitative interviews informed an expert panel consultation which developed clinical guidelines for primary care.

Conclusions: The guideline became part of a complex intervention to support the uptake of psychosocial interventions by family physicians; the intervention is currently evaluated in a pilot controlled trial. Two new alcohol education programmes were created as a response of the community to the problem and a lack of specialist support services for patients with dual dependencies. Both Coolmine Therapeutic Community and the Community Response Agency run a 10-week group that specifically seeks to include people with dual dependencies, from methadone programmes.