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POSTERS

P1 | The need for a core outcome set for congenital melanocytic naevi

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Keywords: Congenital melanocytic naevi, core outcome set, outcome, systematic review

Background: Congenital melanocytic naevi (CMN) are birthmarks that can cover large areas of the body. CMN have a great impact on patients' life due to the deviant appearance and risk of developing melanoma or neurocutaneous melanosis. Unfortunately, good clinical guidelines for the management of this condition are limited due to heterogeneity of outcomes reported in literature. The aim of this study was to identify commonly used outcomes in CMN research and show the heterogeneity in outcomes, to eventually set up a Core Outcome Set (COS).

Methods: The review was registered in PROSPERO, registration number CRD42018095235. A search was conducted in PubMed, EMBASE (Ovid), and the Cochrane Library between 2006 and 2018. All English, Dutch, or French articles, with 10 or more patients, reporting outcomes of CMN management (including quality of life assessment) were included. Data extraction was done by two independent reviewers.

Results: A total of 1189 studies were screened for eligibility of which 59 articles were included in our study. Two-hundred and sixteen different outcomes and 34 different outcome measurement instruments were described. Nine per cent of outcomes were patient reported. We classified the outcomes in the following 25 domains: physical, emotional, social, cognitive, role functioning, family functioning, delivery of care, congenital/familial and genetic outcomes, eye, infection, neoplasms, nervous system, renal and urinary, psychiatric, skin and subcutaneous (before and after treatment), characteristic of hair, pain, repair function of skin, sensation, histology, adverse events, death, costs, and other treatment needed.

Conclusion: Large heterogeneity was seen in outcomes, outcome measurement instruments, and classifications systems in CMN research. This review shows the need for a COS in CMN research and the need for the development of a patient-reported outcome measures (PROMs). The Amsterdam University Medical Centre and Erasmus Medical Centre have set up a project to develop a COS and a PROMs for CMN research. This will be done with the global aid of patients and medical CMN experts.

P2 | Participant input in core outcome set development: Qualitative study

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Keywords: Core outcome set, Delphi, interview, patient participation, survey

Core outcome sets (COS) represent the minimum outcomes that should be measured and reported in all clinical trials. Their usefulness and importance is well recognized, as is the need for patient participation in their development, alongside other stakeholders. Patients' input ensures that future studies provide users of research with relevant knowledge regarding interventions. Patients are increasingly including alongside other stakeholders: a survey of recently developed or ongoing COS projects indicated that patient participation occurred in over 87% of projects and that Delphi surveys are being utilized in over 89% of ongoing COS with patient participants. It is unclear how patients experience Delphi and other methodological approaches to COS development and whether these methods are suitable for facilitating the participation of patients in COS development. A recent study explored feedback on recruitment and retention methods of a Delphi survey, this interview study should provide richer information regarding these findings. We investigate whether current methods of COS development are fit for purpose and acceptable to these participants patients and health professionals who participated in a COS took part in semistructured qualitative interviews about their experiences. Study

participants were recruited via COS developers. Interviews explored participants' understanding of COS and their experiences of the Delphi survey. The analysis was interpretative and thematic. Twenty-four interviews were conducted from seven COS studies, 12 patients, and 12 health professionals participated. The results provide insights into participants' experiences and understanding of COS development and of Delphi surveys.

P3 | A list of tools is not enough! Professionals' advice on how to implement a core outcome set in practice

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Keywords: Core outcome set, dementia, implementation, interview

Background: The number of core outcome sets (COS) has increased in recent years and more methodological research has been published aiming to increase the credibility of COS. However, little is yet known about strategies to facilitate COS implementation and promote adherence among professionals and researchers to use COS in practice.

Methods: Qualitative interviews ($n = 29$) were conducted in the pre-Delphi stage of the development of a COS to evaluate physical activity interventions for people living with dementia. Nine professionals were asked to comment on strategies to implement this COS, once it had been completed. Data generated from the comments were analyzed thematically.

Results: Participants included professionals from a wide range of backgrounds (public, private, and voluntary sectors), and from different settings (hospitals, community, nursing, and care homes). Their comments on COS implementation in practice can be organized into three themes: (1) "Needing a COS in practice"—participants explained how COS can help to meet the needs of professionals to measure patients' physical activity interventions and benchmark their results against others and against published research; (2) "Making it work in practice"—participants stressed not only the need to include feasible measurement tools in COS (low cost and easy to use) but also the need for a "toolkit," including not only the tools, but when and how to use them; and (3) "Broadcasting it widely"—by presenting at conferences, professionals' meetings, and promoting COS among professional and governance bodies.

Conclusions: Professionals recognize the need for COS in practice and would welcome a set of outcomes and tools presented as a "toolkit". Wide dissemination activities are likely to be necessary to achieve the homogeneity of reporting outcomes aimed by COS developers.

P4 | Implications of a qualitative study on core outcome set development

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Keywords: Carers, core outcome set, dementia, health professionals, interview, outcome, patients, qualitative

Background: The use of qualitative methods within core outcome set (COS) development has been recognized as a potentially beneficial methodological innovation. Although preliminary guidance on the use of qualitative methods as a pre-Delphi stage in COS development has been published, additional appraisal on the use of this novel approach is still encouraged. The present study reports on the implications of a qualitative study on the development of a COS to evaluate physical activity interventions for people with dementia, across different stages of the condition and intervention settings.

Methods: In-depth qualitative interviews ($n = 29$) were conducted with people with dementia, their family carers, and health professionals. Data were analyzed thematically and the outcomes identified in the interviews were compared against those reported in a previous literature review. Interview data was also used to define the scope of each outcome domain. Possible implications of this qualitative study on the development of the COS were identified.

Results: The present qualitative study generated 10 new outcomes; nine outcomes were identified in previous literature, but not in this qualitative study. A final list of 77 outcomes was generated to be used in the Delphi stage. A glossary was also developed based on these qualitative findings, clearly defining the scope of each domain prior to the Delphi. The large majority of outcomes were mentioned by participants across stages of dementia. Thus, the COS protocol was changed from a Delphi survey subdivided per stages of dementia to a single Delphi survey common to all stages.

Conclusions: Qualitative studies can generate new outcomes to those generated through literature reviews, and they can be paramount in defining the scope of each outcome pre-Delphi. Qualitative studies can inform the structure of COS by providing an in-depth understanding of how outcomes can be meaningful across stages of disease progression.

P5 | A systematic review of outcomes measures in subarachnoid hemorrhage research

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Keywords: Core outcome set, outcome, subarachnoid hemorrhage, systematic review

Consensus on appropriate outcome measures to use in aneurysmal subarachnoid hemorrhage (aSAH) research has not been established, although the transition toward a core outcome set (COS) would provide significant benefits. To inform COS development, we conducted a systematic review to identify outcome measures included in reports of randomized clinical trials (RCTs) of interventions in patients with aSAH. Ovid Medline, EMBASE, CINAHL, and CENTRAL were searched. RCTs investigating aSAH published between January 1996 and May 2015 were included. The primary and secondary outcomes of RCTs were recorded and classified according to the OMER Outcome Measures in Rheumatology (ACT) Consortium's framework. We identified 1093 potential studies of which 129 met inclusion criteria representing 24,238 patients. There were 285 unique outcome measures. The Glasgow Outcome Scale (GOS) was the most frequently used primary outcome (13/129, 10.1%). Mortality was reported in 84 trials (65.1%) with three months the most common time-point (34/129, 26.4%). The GOS (65/129, 50.4%) and the Modified Rankin Scale (51/129, 39.5%) were the most commonly reported functional measures, however these were reported at different time-points and often dichotomized using different ranges. Patient-reported quality of life measures were used in 11 trials (8.5%). Transcranial Doppler was the most frequently used imaging modality (40/129, 31.0%). Definitions and reporting of vasospasm, delayed cerebral ischemia, and imaging modality results were highly variable. The marked heterogeneity of outcomes in reports of RCTs supports the development of a core outcome set for aSAH trials. Our study has identified a wide range of outcomes for potential inclusion in a future aSAH COS.

P6 | A core outcome set for nonpharmacological health and social care community-based interventions for people living with dementia

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Keywords: Consensus meeting, core outcome set, outcomes, Delphi, dementia

Currently there is a lack of consistency in outcomes measured across studies evaluating nonpharmacological health and social care community-based interventions for people living with dementia, which obstructs comparisons for effectiveness and makes the interpretation of results and meta-analysis difficult. One way to address this is to use and report a core outcome set—a list of core outcomes that should be measured and reported as a minimum across all relevant effectiveness trials. In phase 1, outcomes were extracted from existing trials ($n = 124$) and key stakeholders (people living with dementia, care partners, and health and social care professionals; policymakers and researchers) were recruited to interviews and focus groups ($n = 55$) in order to identify important outcomes. On the back of unsuccessful attempts elsewhere at involving people living with dementia in a Delphi survey, in phase 2 the research team facilitated substantial involvement of people living with dementia as co-researchers in order to design a modified, accessible, and innovative two-round Delphi survey method. Across the stakeholder groups, the excellent response rate in the Delphi (86.3% response rate between rounds—R1 $n = 285$; R2 $n = 246$) reflects the substantive work undertaken to ensure the method was accessible to people living with dementia. The final core outcome set was ratified at a consensus meeting (again, modified to accommodate people living with dementia), where 13 outcomes were finalized as core. The next phase of the study will undertake a systematic review to assess how outcomes should be measured.

P7 | Core information for consent in surgical oncology: An application of core outcome methodology to define what information is important to patients and clinicians

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Keywords: Colorectal cancer, core information set, esophageal cancer, head & neck cancer, patient information

Background: The provision of high-quality, patient-centered information is a requirement in many healthcare services worldwide, but standards for what information to provide are lacking. Over-disclosure may overwhelm patients with too much information that may not be important. Patient-led communication, where discussions are guided by the individual, is helpful but patients may lack sufficient baseline knowledge to

ask important questions. A potential solution is a core information set (CIS). This is a scientifically-agreed, consensus-driven, minimum amount of information to be discussed with patients to catalyze further discussion of issues of importance to the individual. The aim of this project was to define a CIS for each of three areas in surgical oncology: esophageal, head & neck, and colorectal cancer.

Methods: Methods established for the development of core outcome sets were applied. The three CIS involved (i) reviews of scientific literature, and patient information leaflets provided by hospitals, (ii) in-depth interviews with patients and surgeons, (iii) operationalization and administration of Delphi questionnaires, and (iv) consensus meetings for professionals and patients. Each CIS consisted of domains rated most important for discussion by patients and healthcare professionals

Results: A total of 332 patients and 268 healthcare professionals participated. The final esophageal CIS consisted of eight information domains, the head & neck CIS 13 domains (plus 2 procedure-specific domains), and the colorectal CIS 11 domains. In general, patients favored information about non-technical aspects of surgery, particularly functional recovery. Surgeons tended to rate operative details and peri-operative complications as most important for discussion. There were areas of overlap between the three CIS, suggesting that the development of generic CIS for surgical oncology is possible.

Discussion: It is feasible to apply core outcome set methods to the development of CIS. Further work is ongoing that will develop methods for implementing CIS into routine practice.

P8 | The comparison of outcomes reported by healthcare professionals and patients on the management of obesity in pregnancy

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Keyword: Obesity in pregnancy, outcome, health professionals, patients

Objective: The perception of successful management of obesity in pregnancy may differ between healthcare professionals (HCPs) and patients. Thus, it is imperative that a core outcome set in this population be comprised of input by both groups of stakeholders. The objective of this study was to compare findings of qualitative interviews of HCPs and patients regarding outcomes they deem important to measure in this field in future research.

Methods: Pregnant women with a Body Mass Index (BMI) over 30 kg/m^2 were recruited from the Special Pregnancy Program at Mount Sinai Hospital in Toronto, Canada to participate in interviews. HCPs affiliated with this clinic were enrolled in semistructured focus groups. While the design and facilitating questions were different, the goal of both interviews and focus groups was to obtain outcomes important to participants in terms of managing obesity in pregnancy. Discussions were analyzed to identify outcomes from each group.

Results: Six patient interviews and two HCP focus groups were conducted. Only analysis from field notes is complete. Reported outcomes covered both antenatal and postnatal periods. HCPs mostly reported on delivery-related outcomes, such as mode of delivery, analgesia usage, and surgical site access. Contrarily, patients presented more outcomes concerned with pregnancy and their child, such as gestational weight gain, comfort during pregnancy, and neonatal birthweight. Both groups insisted on improving two-way communication: patients wanted to better understand their plan and to feel supported by HCPs, while HCPs wanted to feel more comfortable addressing patients' weight and its effects on pregnancy.

Conclusion: Our preliminary analysis provides critical insight into outcomes important to both HCPs and patients in the management of obesity in pregnancy. There are notable differences in how these two stakeholder groups prioritize outcomes related to pregnancy and obesity, which will be essential in the development of an effective core outcome set in this field.

P9 | Systematic review of reported outcomes in clinical trials in basal cell carcinoma

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Keywords: Basal cell carcinoma, outcome, outcome reporting, systematic review

Background: Basal cell carcinoma (BCC) is the most common cutaneous malignancy. While many systematic reviews exist in the literature regarding various therapeutic options for BCC, to our knowledge, there has never been a review of the various outcomes reported in BCC clinical trials. Heterogeneity in outcome measures across trials increases the risk for selective outcome reporting bias, defined as results-based selection of outcomes for publication, which has the potential to compromise the validity of conclusions drawn from the results. Core outcome sets counteract this problem by standardizing the minimum reported outcomes to reflect the most clinically relevant factors. We aimed to systematically review the outcomes utilized in randomized controlled trials (RCTs) of BCC over a 10-year period in order to create the framework for a core outcome set for BCC treatment.

Methodology: By searching PubMed, Embase, and Cochrane databases in May 2016, we identified all RCTs published between 2006 and 2016 that assessed treatment options for BCC. The search initially yielded 132 results. Thirty-two were eliminated based on title review; 15 were eliminated on the basis of forced agreement review of abstracts by four independent reviewers; 15 were eliminated after full-text review. Data extractors then identified the stated outcomes and outcome measures as well as pertinent study methodology and data collection information for the 70 remaining articles. Stakeholders including five dermatologists, two primary care physicians, one nurse, one physician assistant, one medical assistant, and nine international dermatologists were consulted to provide additional input regarding which outcomes deserve representation. After the comprehensive list of outcomes was generated, outcomes were collapsed and de-duplicated by two investigators from the Measurement of Priority Outcome Variables in Dermatologic Surgery (IMPROVED) group. Disagreements were resolved by forced agreement. Similar outcomes were grouped into domains.

Results: A total of 512 outcomes were assessed. The IMPROVED physicians combined and de-duplicated similar outcomes to generate a list of 84 relevant outcomes that were then categorized into specific domains: recurrence free survival (21%), clinical assessment by physician (20%), investigator-reported treatment effectiveness (19%), patient-reported tolerability, including adverse events (12%), objective data and lab values (8%), histopathologic assessment (7%), patient satisfaction (7%), and procedural factors (6%).

Conclusions: These data provide a framework for the development of a BCC core outcome set via a Delphi consensus process and final consensus meeting, which are currently underway.

P10 | Development of a core outcome set and identification of outcome measurement tools for interventions after stillbirth

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Keywords: Core outcome set, outcome measurement, stillbirth

Background: Interventions offered to parents following the diagnosis of stillbirth include birthing options, counselling, and care in subsequent pregnancies. There is limited evidence assessing the impact of many of these interventions and therefore there is a need to develop and evaluate interventions for parents experiencing stillbirth. To do so, a minimum set of acceptable, feasible, and reliable outcomes that should be measured in such studies, is needed.

Aim: To develop a core outcome set (COS) and identify outcome measurement tools for care after stillbirth.

Methods: Stage 1: Identifying previously reported outcomes, we are conducting a systematic review of the quantitative and qualitative literature to investigate what outcomes have been reported in existing studies and what tools have been used to measure those outcomes. Stage 2: Identifying outcomes that are important to parents and healthcare professionals, thirty parents from diverse social, ethnic, and cultural backgrounds who have experienced stillbirth at a range of gestations will be interviewed. Findings will be triangulated with a healthcare professionals' focus group. Stage 3: Determining the COS, parents, doctors, midwives, and researchers will participate in a three-round online Delphi study to prioritize outcomes. A consensus meeting will be held to determine the COS. Stage 4: Determining how core outcomes should be measured, we will conduct an in-depth quality assessment of outcome measurement instruments using consensus-based methodology for short-listed outcomes identified by the Delphi Study. Patient and public involvement: We have recruited a parent involvement group of 13 parents who have experienced the loss of a baby. Patients will inform all stages of the development of the COS. We plan to finalize the COS by 2020.

Conclusions: Developing a COS for care after stillbirth will enable researchers internationally to focus research and clinical care on important outcomes, and develop effective interventions for parents experiencing stillbirth.

P11 | Carers and their involvement in developing a core outcome set: The veterinary experience

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Keywords: Carer, cat, chronic kidney disease, core outcome set, veterinary

As with the carers of children, the carers of veterinary patients have an important role in decision making on treatment choice and duration. Chronic kidney disease (CKD) is a significant cause of morbidity and mortality in feline patients. A systematic review of treatment efficacy for this condition found that nearly 100 individual patient parameters were examined and recorded in the published literature. There is no agreed core outcome set (COS) for CKD and there are few established COS in veterinary medicine. The aim of the study is to develop a COS for cats with CKD by involving an anonymous, international panel of carers, veterinary surgeons, and

other relevant members of industry and regulatory bodies, using methodology adapted from the eczema outcomes (Harmonising Outcome Measures for Eczema (HOME) Initiative). There is a high (78% to 95%, $n = 73$) retention rate across the first questionnaires and eight parameters have reached the a priori agreed definition of consensus. By the second round of questionnaires, 13 additional parameters had been proposed, and from the free text a commentary is emerging on veterinary patient carer stresses, fear of change in the relationship dynamic between patient and carer, the carer's perception of whether treatment is "fair," carer practical training, and available supportive or educational literature. Our study highlights the importance of carers at all stages of the consensus process to ensure that the best interests of cats with CKD are well reflected in the final COS. Using the Delphi methodology to achieve consensus on COS for treatment trials for dependent patients, we will ensure that the final COS strengthens the evidence base for new and existing treatments and improves understanding of which treatments are most effective. Carers are often the "gatekeepers" to treatment and their involvement in the COS leads to more patients receiving the most effective and appropriate treatments for their condition and setting.

P12 | Discerning and promoting patient-important outcomes in the development of a core outcome set: Examples from coreHEM and coreNASH

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Keywords: Core outcome set, Delphi, gene therapy, hemophilia, nonalcoholic steatohepatitis

Background: Advancements in biomedical technology offer promise for patients. Innovative therapies can change the standard of care, which can change patient expectations and priorities regarding the outcomes most important to collect. For core outcome development for these diseases, it is essential that evolving patient perspectives are captured and brought to the attention of other stakeholders. This paper describes the method used in two core outcome set (COS) projects: coreHEM for gene therapy for hemophilia, a genetic blood clotting disease; and coreNASH for nonalcoholic steatohepatitis (NASH), a progressive form of fatty liver disease.

Methods: A modified Delphi process was utilized (online surveys and in-person consensus meeting). Candidate outcome lists were compiled; patient interviews complemented a literature review. Voters condensed and prioritized the lists by rating each outcome from 1 to 9 (not important - essential). Outcomes were retained if ≥70% rated the outcome 7 to 9 (high consensus), otherwise they were eliminated. For voting rounds preceding the in-person meeting, criteria were designed to give extra weight to patient opinions: even if high consensus was not achieved, outcomes were retained if the average patient vote was ≥7 ("retained for patient-importance"). These outcomes were topics for meeting discussion. Following this discussion, the extra criterion for "patient-importance" was dropped; the outcome had to meet the unmodified "high consensus" definition to be included in the COS.

Results: Patients/patient advocates represented 10.2% and 12.3% of the voters in coreHEM and coreNASH, respectively. In coreHEM, two outcomes (chronic pain and mental health) were included in the meeting discussion due to the "patient-important" criteria. Both were ultimately selected as part of the coreHEM COS. Voting for coreNASH is ongoing.

Conclusions: Using a "patient-important" criterion to retain outcomes from the candidate list during COS development allows for more explicit consideration of patient priorities that may otherwise be eliminated to due lack of awareness.

P13 | An exploration of factors affecting second round response rates in Delphi studies for core outcome set development

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Keywords: Core outcome set, Delphi, response rate

Background: The Delphi method is fast becoming one of the most popular methods to achieve consensus in core outcome set development. It is important to try and maximize response rates to Delphi studies, minimizing attrition rates and potential for bias. The factors that impact response rates in a Delphi study used for core outcome set (COS) development are unknown. The objective of this study was to explore the potential impact of different factors on response rates in Delphi surveys within COS development projects.

Methods: Published and ongoing studies that included Delphi in their methods to develop a core outcome set were included in this study. Second round voting response rates were analyzed, and multilevel linear regression was conducted to investigate whether study characteristics were associated with second round response rate.

Results: Thirty-one studies were included in the analysis. Two variables were significantly associated with a lower response rate: larger panels and studies with more items included in the second round.

Conclusions: COS developers should pay particular attention to methods when designing a Delphi COS development study,

in particular the size of the panels and the size of the list of outcomes. We identified other potential factors that might influence response rates but were unable to explore them in this analysis. These factors should be reported in future reports to allow for further investigation. Studies within studies to answer research questions are warranted to address the research uncertainties identified in this study. Suitable early planning is essential to optimize response rates in the Delphi process.

P14 | A practical application of core outcome set-STAndards for Development: The example of cancer core outcome sets

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Keywords: Cancer, core outcome set, minimum standards

Introduction: The core outcome set-STAndards for Development (COS-STAD) contains 11 standards that are deemed to be the minimum design recommendations for all COS development projects. The recommendations focus on three key domains: the scope, the stakeholders, and the consensus process. A practical application of the standards, to provide further guidance on how to apply COS-STAD, is necessary to identify how the criteria should be interpreted as well as to identify and resolve any potential issues and challenges for users. Cancer is currently the disease area with the highest number of published COS, has substantial variability in populations and treatments, and covers a wide range of diverse clinical areas. Therefore, cancer COS is a useful starting place to apply COS-STAD and will be the focus of this study.

Methods: Two reviewers independently assessed each of the COS against the criteria of development.

Results: Forty-one cancer COS were included in this study. No COS met all of the 12 criteria representing the 11 minimum standards assessed in this study (range 4 to 11 (criteria), median 6 (criteria)). A summary of each standard will be presented.

Discussion: No COS met all of the minimum standards, with most studies only meeting about half of the standards. Standards in the scope specification domain were well met. Poor reporting of the stakeholders involved in COS development made it challenging to sometimes assess the equivalent criteria for minimum standards. The majority of COS studies did include those who will use the COS in research and health care professionals in the development process, while only a quarter included patients or patient representatives in the process. The consensus process criteria were the most difficult to assess, particularly those that required an assessment of being a priori. Stakeholders involved and consensus process are lacking and there is much need for improvement.

P15 | Choosing important health outcomes for comparative effectiveness research: 4th annual update to a systematic review of core outcome sets for research

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Keywords: Database, core outcome set, systematic review update

Introduction: The Core Outcome Measures in Effectiveness Trials (COMET) Initiative aims to collate and stimulate the development and application of core outcome set (COS), by maintaining a public repository of studies relevant to the development of COS. A systematic review was conducted to initially populate the COMET database, and it has been subsequently updated to include all published COS up to, and including, 2016. The aims of the current study were to: (i) update the systematic review in order to identify any further studies where a COS has been developed, (ii) to describe the methodological approaches taken in these studies, and (iii) to highlight areas for future COS development and improvement.

Results: Data extraction is currently underway. It is anticipated that 49 new COS will be included in the review update. Results will be presented.

Discussion: The database is an integral resource to not only the development of COS, but also to the uptake of the COS in research and in the avoidance of unnecessary duplication and waste of scarce resources. For all of these reasons it is imperative that the database is maintained and kept up to date. This is done continually and eligible studies are added to the database as they are found. An annual update to the aforementioned systematic review means that the database remains optimal for use.

P16 | Development of a core outcome set for acute uncomplicated appendicitis in children and young people

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Keywords: Acute uncomplicated appendicitis, children and young people, core outcome set

Introduction: Appendectomy has been the gold standard treatment for acute appendicitis in children and young people (CYP) but there has recently been increased interest in nonoperative treatment. Core outcome sets (COSs) are developed and adopted to avoid inconsistencies in outcome selection, measurement, and reporting. This is especially important when evaluating novel treatments, since outcomes of importance may differ from those reported with traditional treatments. A review of the relevant literature revealed no COS for acute appendicitis in CYP; this study aimed to develop one.

Methods: Systematic reviews and qualitative interviews with parents and patients treated for acute appendicitis were used to identify an initial list of outcomes. A study-specific advisory group of parents and CYP helped to inform study processes. Outcomes were subsequently prioritized by patients, parents, and surgeons in a three-phase Delphi survey and consensus meetings.

Results: One hundred and forty-seven participants completed the first Delphi phase, during which 40 outcomes were scored. Sixty-one per cent of participants ($n = 90$) from phase one completed all three phases of the Delphi (32 parents; 3 CYP; 55 surgeons). Fourteen outcomes were prioritized in the third phase of the Delphi, including intra-abdominal abscess, reoperation, readmission, bowel obstruction, major or minor complications, blood loss, wound infection, fever after treatment, unplanned central venous catheter, antibiotic failure, pain score, recurrent appendicitis, death, and quality of life. These outcomes will be brought forward to consensus meetings and the finalized COS will be presented at the COMET meeting.

Conclusion: The finalized COS should be adopted as a minimum in future trials of acute appendicitis in CYP. Doing so will ensure that the outcomes of greatest importance to stakeholders are consistently measured, which is crucial for pediatric appendicitis research to be meaningful and relevant, and will improve data synthesis. Further work is needed to establish 'how' best to measure the outcomes in the finalized COS.

P17 | Protocol for the development of a core outcome set for trials assessing therapeutic intervention for diabetic foot ulceration

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Keywords: Core outcome set, diabetic foot ulceration, protocol

Introduction: The global prevalence of patients with diabetes exceeds 415 million and this number is expected to increase to over 640 million by 2040. The estimated lifetime risk of a diabetic patient developing a foot ulcer is 25%. Diabetic foot ulceration (DFU) is associated with significant morbidity, including major limb amputation and mortality. DFU is difficult to treat, often requiring therapeutic intervention from multiple specialties. Outcome reporting in trials assessing the clinical effectiveness of therapeutic interventions for the treatment of DFU is heterogeneous. A solution to this problem is the development of a core outcome set (COS), providing an evidence-based approach to the problem of outcome selection and reporting in DFU.

Aim: To develop and disseminate a COS set for clinical trials evaluating therapeutic interventions for DFU. The COS would represent the minimum reporting standards in all DFU research trials.

Methods: There will be three phases conducted in-line with the published Core Outcome Measures for Effectiveness Trials (COMET) guidelines. Phase one involves the generation of a long list of outcomes from three sources: semistructured patient interviews, survey of an international steering committee, and a systematic review of the literature. The long list will be condensed and overlapping outcomes merged by two independent researchers. In the second phase, the long list will be condensed, using Delphi techniques, by survey of relevant key stakeholders; patients will be surveyed by post and professionals will be surveyed online. In the third phase, stakeholders will be invited to a consensus meeting where anonymous voting will be used to establish a final COS.

Discussion: DFU represents a significant global problem and is an area of active research. The time is ripe for the development of reporting standards by way of a COS set to ensure meaningful comparison between novel therapeutic interventions for DFU.

P18 | Identifying HTA outcome preferences to input into core outcome sets: Hematological malignancies

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Keywords: Big data, core outcome set, health technology assessment, hematological malignancies, outcome, real-world evidence

Introduction: Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Hematology (HARMONY), an IMI Big Data for Better Outcomes project, aims to optimize the use of real-world evidence across seven classes of hematological malignancies (HM). Development of core outcome sets (COS) that meets the requirements of all stakeholders, including the various European Union (EU) regulatory agencies, HTA bodies, and payer organizations evidence requirements, is key factor for the harmonization of the data and future success of the project to enhance market access to novel oncology treatments.

Aim: To ascertain the outcome preferences and provision of outcomes to a Health Technology Appraisal (HTA) organization to inform COS development for a big data project.

Methods: Outcome data was extracted from all publically available and completed technology appraisals (TAs) performed by National Institute of Health and Care Excellence (NICE) for HMs (2001 to 2017). NICE manuals and reference cases were examined for stated preferences. Outcomes were analyzed by the following domains; time to event, tumor response, safety, and patient-reported outcomes with regard to frequency and year of reporting.

Results and Discussion: Forty completed technology appraisals met the inclusion criteria (8% of all published TAs). Primary outcome preferences and reporting was stable across the majority of HM classes and outcome domains. More recent TAs contain a wider range of tumor response measures reflecting advances in technology and a trend toward time to next treatment reporting. The analysis and consideration of previous outcomes requested and submitted to HTA within a disease area can provide a timely and resource light mechanism for a singular HTA input into COS development. To maximize the use of this strategy and provide an EU wide perspective, we suggest utilizing existing HTA ontologies to identify exemplars organizations to use with this approach.

Conclusion: The use of previous completed reports can provide a valuable indication of outcome preference by a HTA agency for use in COS.

P19 | Involving people living with dementia as co-researchers in core outcome set methodology

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Keywords: Core outcome set, dementia, patient participation

The high variation of outcomes measured across studies evaluating nonpharmacological health and social care community-based interventions for people living with dementia is compounded by the strong indication that chosen outcomes may not reflect what is important to people living with dementia. This obstructs comparisons for effectiveness and makes the interpretation of results difficult. Furthermore, the rigor of trials must be called in to question if outcomes (or outcome constructs) do not reflect what is important to those with lived experiences. One way to address this is to use and report a core outcome set (COS) - a list of core outcomes that should be measured and reported as a minimum across all relevant effectiveness trials. If COSs are to be relevant and responsive, a critical issue for COS designers is how to incorporate the views of those with lived experience. While this vital activity is often not done, done poorly, or approached as a single isolated activity, studies have shown people with lived experience often have different perspectives on what outcomes are important when compared with professional groups. This presentation, part of the Neighbourhoods and Dementia programme (funded by the ESRC/NIHR under key commitment 12 of the first Prime Minister's Challenge on dementia), reports on the development of a COS methodology that has positioned people living with dementia as co-researchers throughout the wider research process. Specifically we report on how we have facilitated and included the views of people living with dementia at every stage of the research process – from involvement in determining what outcomes are important, consultation on the development of research tools, and participation in an accessible Delphi survey and consensus workshop approach.

P20 | CHOICE—core health outcomes in childhood epilepsy

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Keywords: Childhood epilepsy, consensus meeting, core outcome set, Delphi, literature review

Objective: Establishing a core set of outcomes to be evaluated and reported in trials of interventions for a particular condition will improve the usefulness of health research. There is no established core outcome set (COS) for childhood epilepsies. The aim of this study was to select a COS to be used in evaluative research of interventions for children with rolandic epilepsy (RE) as an exemplar of common childhood epilepsy syndromes.

Methods: We followed guidance from the COMET (Core Outcome Measures in Effectiveness Trials) Initiative. We identified which outcomes should be measured from a search for trials of interventions for childhood epilepsy, statutory guidance, and consultation with our Advisory Panel. Young people with RE, parents, and professionals were invited to participate in a Delphi survey in which participants rated the importance of candidate outcomes. A face-to-face meeting was convened to seek consensus on which outcomes were critical to include and to ratify the final COS.

Results: Thirty-seven papers were eligible from the literature review and outcomes were recorded. We identified 48 candidate outcomes: these were included in the survey. A total of 165 people registered to take part in the survey and were

sent invitations; of these 102 (62%) completed Round 1, and 80 (78%) completed Round 2 (three young people, 16 parents, 61 professionals). Four additional outcomes suggested by participants were included in Round 2. The consensus meeting included two young people, four parents, and nine professionals who were eligible to vote and ratified the COS as 39 outcomes across 10 domains.

Significance: Our methodology was a proportionate and pragmatic approach to produce a COS for evaluate research of interventions aiming to improve the health of children with RE. We will review and recommend ways to measure the COS using clinical assessment and/or patient reported outcome measures.

P21 | Need for core outcome set on work participation (COS-WP)

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Keywords: Core outcome set, outcome reporting, work participation,

Background: In the field of occupational health, professionals deal with many different types of workers' diseases. Despite the increasing number of core outcome sets (COSs) in other medical disciplines, a COS for work participation (COS-WP) is still lacking.

Aim: We explored the need for a COS for intervention studies in the field of occupational health and insurance medicine by performing a pilot review to gain insight into reported outcomes, their terms and definitions, and the type of outcome measurement instruments reported in randomized controlled trials (RCTs).

Methods: RCTs reported in seven Cochrane reviews in the field of occupational health were summarized to determine which types of outcomes are generally reported in relation to interventions that aim to promote work participation.

Results: The reviews included 82 RCTs and reported a variety of work participation outcomes, including return to work (RTW), sick leave, absenteeism, work status, functional status, productivity, and work functioning. Further, outcomes were measured at different follow up times ranging from a few weeks to four years after baseline; definitions or cut points for RTW or sick leave varied such as time to first day of 100% RTW, cumulative days off work, sick leave rate; mean monthly sick leave days; diverse statistics were included such as rates, means, odds, or hazard ratios; and different sources to measure work participation were used such as self-report data, questionnaires, or administrative databases.

Conclusion: The variation in outcomes and measurements highlights the need for a COS-WP that is relevant within the field of occupational health. The Coronel Institute of Occupational Health of the Academic Medical Center in Amsterdam has started an international collaborative project to develop a COS-WP, in collaboration with Amsterdam Public Health COS (APH-COS) focus group, Cochrane Insurance Medicine, and Cochrane Work.

P22 | Protocol for the development of a global core outcome set for reporting treatment of uncomplicated appendicitis in children

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Keywords: Children, core outcome set, protocol, uncomplicated appendicitis

Introduction: In the last decade, there have been several developments in the treatment of appendicitis in children, with the most recent being nonoperative treatment. From recent studies, it has become apparent that a wide variety of outcome measures have been reported in studies regarding the treatment of uncomplicated appendicitis, especially in studies comparing nonoperative to operative treatment. To allow for adequate comparison of studies or data-pooling, a set of globally applied core outcomes is essential. This study aims to develop a global core outcome set (COS) to allow for unified reporting on the treatment of acute uncomplicated appendicitis in children.

Methods/Design: An international steering committee has been established including representation from all key stakeholder groups. Potential outcomes will be identified by updating the most recent systematic review. In a global online 3-step Delphi procedure, it will be attempted to find consensus among patients, parents, and (pediatric) surgeons regarding a set of essential outcomes to be reported in research on the treatment of uncomplicated appendicitis in children. At least nine countries will be participating, inviting over 720 respondents. Third, a face-to-face consensus discussion will be held to ratify the COS and define the outcomes. Ethical board approval will be ascertained along with informed consent from all participants.

Discussion: This protocol presents the first step in developing a COS for pediatric appendicitis. The next step will be to determine how the selected outcomes should be measured.

Prospective registration: This study was prospectively registered with Core Outcome Measures in Effectiveness Trials Initiative: 1119.

P23 | Core outcome set for cauda equina syndrome: Delphi survey and consensus meeting

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Keywords: Cauda equina syndrome, core outcome set, Delphi, consensus meeting

Background: Currently there is no defined core outcome set (COS) for patients who have cauda equina syndrome (CES). CES is most commonly caused by compression of the spinal cord. Severe disability can result including leg weakness, bowel, bladder, and sexual dysfunction. It is the most common spinal condition for which an emergency operation is performed. Through a published systematic literature review, we have shown that there is significant difference in the reporting of the outcomes for CES. We intend to develop a COS for patients with CES to be used for future research studies.

Methods: Outcomes from the systematic literature review and outcomes from the semistructured qualitative interviews of 22 CES patients were combined. These were grouped into similar and higher order outcomes that are being rated in an ongoing International two round Delphi survey. The consensus meeting has been arranged for early November with a sampling frame to select delegates.

Results: Seven-hundred and thirty-seven verbatim outcome terms from the systematic literature review were combined with 260 from the qualitative interviews. Nine-hundred and nine seven verbatim outcome terms in total were reduced by the study team to 37 outcomes for rating in the Delphi survey. The Delphi has 271 participants at the end of round 1; 189 patients and 82 healthcare professionals. Sixty-one additional outcomes were suggested of which one was accepted after review with the study team. Currently round 2 is in progress. We will report the results of round 2 and the consensus meeting at conference.

Conclusion: More engagement from patients than healthcare professionals during the Delphi suggests that for patients it is an important condition to help decide the outcomes. The core outcome set would be published and used for future research studies and improving outcome reporting in CES literature.

P24 | The benefits of international volunteering in a low-resource setting for healthcare professionals: Development of a core outcome set

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Keywords: Core outcome set, Delphi, qualitative research, systematic review

Background: Qualitative narrative analysis and case studies form the majority of the current peer-reviewed literature about the benefits of professional volunteering or international placements for healthcare professionals. These often describe generalized outcomes that are difficult to define or have multiple meanings (such as "communication skills" or "leadership") and are therefore difficult to measure. However, there is an interest from employers, professional groups, and individual volunteers in generating metrics for monitoring personal and professional development of volunteers and comparing different volunteering experiences in terms of their impact on the volunteers. In this paper, we describe two studies in which we (a) consolidated qualitative research and individual accounts into a core outcome set and (b) tested the core outcome set in a large group of stakeholders. The core outcome set will be used later to develop a psychometric assessment tool.

Method: We conducted a systematic review and meta-synthesis to extract outcomes of international placements and variables that may affect these outcomes. We presented these outcomes to 58 stakeholders in global health, employing a Delphi method to reach consensus about which were "core" and which were likely to be developed through international volunteering.

Results: The systematic review of 55 papers generated 133 unique outcomes and 34 potential variables. One-hundred and fifty-six statements were then presented to the Delphi stakeholders, of which they agreed 116 were core to a wide variety of healthcare professional practice and likely to be developed through international experiences

Conclusions: We summarized existing literature and stakeholder opinion into a core outcome set of 116 items that are core to healthcare professional practice and likely to be developed through international experiences. The core outcomes (COs) were both negative and positive and included skills, knowledge, attitudes, and outcomes for healthcare organizations.

P25 | Do core outcome sets developed for phase 3/4 effectiveness trials translate to pre-clinical research?

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Keywords: Core outcome set, preclinical research, effectiveness trials, mouse model, systematic review

Translational failure from preclinical animal studies to clinical trials has been noted in a number of disease areas. Whilst

multiple contributory factors including poor study conduct and reporting have been acknowledged little attention has been given to whether outcomes measured in preclinical studies are relevant to those considered important in clinical trials. Core outcome sets (COS) aim to reduce waste in research by defining a minimum set of outcomes to be used in all trials of a particular condition. However, these have been developed for phase 3/4 effectiveness trials and their utility in pre-clinical research is not known. The wide variety of outcomes reported from the same test in animals suggests selective outcome reporting. To better understand the translatability of outcomes a systematic review of outcomes used in preclinical pharmacological interventions for type 2 diabetes in mouse models is underway. We will extract exact descriptions of outcomes measured and categorize these according to the COMET taxonomy. We will compare this list of outcomes with a COS being developed for randomized effectiveness trials involving patients with type 2 diabetes that has had input from healthcare professionals, researchers, people with type 2 diabetes and healthcare policy makers. This work will identify whether there are common outcomes between mouse studies and human clinical trials. Where outcomes in the COS have not been measured we will explore the possible reasons for this, for example, the availability of assessment methods in mice. This review of pre-clinical studies will enable better understanding of the outcomes measured at different phases of research and the translatability of COS. The use of established COS in pre-clinical studies may also provide a way for patients to influence preclinical research to make it more relevant to their needs, while also contributing to the reduction of waste and refinement in research.

P26 | Recruitment strategies for an online Delphi survey, part of the development of a core outcome set for type 2 diabetes—the SCORE-IT study

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Keywords: Core outcome set, type 2 diabetes, recruitment, Delphi

The SCORE-IT study aims to develop a Core Outcome Set (COS) for randomized effectiveness trials in type 2 diabetes. To access and recruit relevant stakeholders, including people with type 2 diabetes and healthcare professionals in primary and secondary care, a number of recruitment strategies were used. Professional and patient organizations, with relevant memberships, were approached by email with a request to share a link to online study information and Delphi survey. Emails were also sent to specific databases: (1) a database of people with type 2 diabetes who had registered interest in participating in research and (2) a commercial database of UK NHS employees. To support emails and participant information, a one minute study-specific, animated video was embedded in the study homepage and included as an email link. One-hundred and one organizations (10 UK, 67 European, nine North American, and 15 rest of the world) with professional membership, patient membership, or both were approached along with 164 UK local patient groups. Twelve organizations distributed the survey to their members by direct email ($n = 6$) or by including on their website ($n = 6$). Three could not distribute study information due to policy or privacy reasons. Twenty-six local patient groups circulated study information to their members. A direct email to people with type 2 diabetes, who had registered on the research database, yielded 103 registrations on the day the email was sent. A total of 5539 direct emails were sent to the commercial database (Wilmingtons), 10.7% of these were delivered with 23% of these clicking on the study link. The recruitment of participants to the SCORE-IT study has used a multichannel approach to access a broad range of stakeholders. Further work will be undertaken at the end of the Delphi survey to explore the routes to recruitment and the effectiveness of the strategies used. Results will be presented.

P27 | Using the Knowledge to action model to guide the development and dissemination of a core outcome set for studies on invasive placentation

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Keywords: Core outcome set, invasive placentation, knowledge to action model

Invasive placentation (IP) is a life-threatening obstetrical complication that occurs when the placenta abnormally attaches to the uterine wall that may result in maternal and neonatal morbidity and maternal death. Despite its relative rarity, its incidence has risen considerably in the past 50 years. As such, there is a need for prospective studies to identify best practices for screening, diagnosing, and managing IP. Standardization of outcome reporting is vital to the translation of study results to clinical practice and policy, and can be effectively achieved through the development of a core outcome set. This poster will describe the use of the knowledge to action (KTA) model to guide the development and dissemination of a core outcome set for IP. The KTA model is a conceptual framework that integrates the roles of knowledge creation and knowledge application but conceptually divides them into two cycles: the knowledge creation and action cycles. In reality, however, the process is complex and dynamic and

the boundaries between cycles are fluid and permeable. The development and dissemination of the core outcome set will be an iterative process with both cycles occurring simultaneously. Following the KTA model, the knowledge creation cycle will consist of a systematic literature review, one-on-one interviews with relevant stakeholders, a Delphi survey, and a consensus group meeting. The action cycle will consist of: (1) adapting the core outcome set to local contexts to ensure it is relevant and feasible and to improve acceptance and adherence; (2) assessing potential barriers to the use of the core outcome set; and (3) dissemination and implementation of interventions to promote awareness of the core outcome set. It will also include how best to monitor the use of the core outcome set, an evaluation of its uptake, and strategies to sustain use of the IP core outcome set.

P28 | Focus groups and interviews with professionals involved in the care and management of obesity in pregnancy

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Keywords: Focus group, interview, obesity in pregnancy, outcome

Background: Obesity (BMI > 30 kg/m^2) in pregnancy presents practical challenges for healthcare professionals' (HCPs), and communication that elevated BMI is the primary reason for adverse pregnancy outcomes.

Objective: To determine emergent themes and reported outcomes in focus groups with clinicians involved in managing obesity in pregnancy.

Methods: HCPs were recruited from Mount Sinai Hospital and Toronto Public Health. Semistructured focus group interviews were conducted, using an interpretive description approach. Field notes were color-coded and thematically analyzed to determine outcomes.

Preliminary Results: The first session comprised of a maternal fetal medicine (MFM) fellow, MFM nurse, social worker, clinical nurse specialist, and an ultra-sonographer, and the second comprised of three MFM fellows, an MFM specialist, a labor, and delivery anesthetist, two dieticians, and an obesity-specialized family physician. Both groups discussed challenges with the terminology and communication of obesity. They reported difficulty with fulfilling day-to-day tasks due to fear of the patient's mental and physical health and safety, and the physical limitations of fat distribution in clinical and surgical practice, such as speculum insertion, cesarean incisions, or epidural insertion. Clinical outcomes included mode of delivery, incision type, wound healing, response to analgesia used, details of labor, nutrition, hyperlipidemia, depression, anxiety, macrosomia, maternal and fetal death, postpartum pain, breastfeeding, diabetes in child. Additional outcomes included lifestyle modification (diet and exercise), coordination between HCPs, patient mobility, resource utilization (sleep apnea-related hospital stay, longer operations), and alignment of patient and provider concerns.

Discussion: Focus group dialogue transpired very easily, as HCPs seemed in need of expressing opinions for this patient group specifically, and was further enhanced by the interplay between stakeholder roles. Determined themes emphasize the strained patient–physician relationship for obesity in pregnancy. Participants tended to discuss higher class obesity, therefore individual interviews will be conducted to explore HCPs' perspectives on lower class obesity.

P29 | Obesity in pregnancy patient-reported outcomes: A qualitative study

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Keywords: Interview, obesity in pregnancy, patient reported outcomes, qualitative

Background: Patient perspectives on what constitute important clinical outcomes with regard to obesity and pregnancy are underrepresented in trials. Qualitative studies that aim to identify patient-reported outcomes (PROs) in this population have not been conducted.

Objective: To determine themes and PROs through qualitative interviews with women with obesity [BMI > 30 kg/m2] in pregnancy.

Methods: Patients were recruited at Mount Sinai Hospital. Semistructured, in-depth interviews were conducted in person and via telephone, using an interpretive description approach. Maternal age, occupation, education, and ethnicity were self-reported. BMI and co-morbidities were obtained from patient charts. Color-coded thematic analyses of field notes and transcribed interviews were conducted, identifying PROs and links between characteristics and findings. Data analysis was simultaneous to collection. Interviews continued until saturation, and a 10% verification check was conducted.

Preliminary Results: Of the18 patients recruited, six were interviewed. Mean BMI was 44.5. Presented results were determined from analysis of field notes. Adoption of healthy eating was a valued outcome by all patients, except by those with the two highest BMIs, who were also the sole patients that reported experiences of stigma and discrimination in healthcare settings. Additional outcomes include gestational weight gain (6/6), mobility and physical functioning (6/6), feelings of support (6/6), diet or weight of baby or child (5/6),

breastfeeding (5/6), labor and delivery outcomes (5/6), and the baby or child's development (3/6). Transcripts of the first six interviews are being analyzed to inform purposive sampling and a refined interview guide to elucidate associations between characteristics and results and elicit more PROs. Further interviews are also being conducted.

Discussion: The results of this qualitative study will inform Delphi methodology in the development of a core outcome set and will offer insight to clinicians on the aspects of care that matter most and are probably incompletely addressed in this population.

P30 | Development of a core outcome set for studies on obesity in pregnant patients (COSSOPP): A study protocol

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Keywords: core outcome set, obesity in pregnancy, protocol

Background: Obesity (BMI > 30 kg/m^2) in pregnancy and childbirth elevates the risk of adverse maternal, fetal, neonatal, and infant outcomes. Research progress and clinical application of the obesity in pregnancy literature are inhibited by the quality of outcome reporting. There is a lack of stakeholder input, thus outcomes as prioritized by patients and all carers are overlooked, and outcomes reported and their measurements are heterogeneous between trials. Researcher biased and minimized relevancy of outcomes result as well as limited study comparability and data aggregation. There is currently no core outcome set (COS) in obesity in pregnancy research.

Objective: To develop a COS for studies on obesity in pregnant patients (COSSOPP).

Methods: As guided by the COMET Initiative, COSSOPP entails the following five steps: (I) A systematic review according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines in order to determine the outcomes reported thus far; (II) A qualitative phase, to determine outcomes deemed important by all stakeholder groups (patients, clinicians, researchers, policy makers, hospital administration, etc.), achieved by a meta-synthesis of qualitative methods with patients, as well as conducting prospective qualitative interviews with all stakeholder groups; (III) Delphi methodology to achieve consensus on the outcomes determined in the former steps from internationally represented stakeholders; (IV) A face-to-face consensus meeting with stakeholder representatives in order to consolidate outstanding outcomes that did not classify within prespecified consensus criteria in Step-III, and solidify the core set of outcomes; and (V) Determination of the core outcomes' definitions and measurements via Delphi consensus with the professional stakeholder groups.

Discussion: COSSOPP will harmonize outcome reporting in studies evaluating the effectiveness of antepartum and peripartum interventions in pregnant women with obesity, while engaging a medley of relevant stakeholders to arrive at the core set of outcomes that should be reported and measured.

P31 | Why do Delphi participants change their scores between rounds?

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Keywords: Delphi, methodology, score change

Background: Delphi studies, used to develop consensus, allow participants to change their responses to a questionnaire after reviewing the summarized responses of other participants. It is assumed that seeing other's scores influences subsequent scoring, but there is no evidence for this. This nested study aimed to investigate why between-round score-change occurred in two Delphis (prostate cancer [COMPACTERS; https://doi.org/10.1186/s13063-015-0598-0] and anal cancer [CORMAC; https://doi.org/10.1136/bmjopen-2017-018726]).

Methods: The prostate cancer Delphi considered 79 outcomes over three rounds including 118 patients and 56 healthcare professionals (HCPs). The anal cancer Delphi considered 78 outcomes over two rounds, including 55 patients and 94 HCPs. Delphis were conducted online using DelphiManager software and scored with a 1 to 9 Likert scale (1 to 3 not particularly important, 4 to 5 important, 7 to 9 critically important). Whenever a participant changed their score over an importance threshold (e.g., from 3 to 4), a free-text pop-up box asked them to give a reason. Reasons for score change were coded by two researchers independently using an inductive-iterative approach.

Results: There were 738 responses from 187 participants (71 anal; 116 prostate). Median responses per participant (total; anal; prostate) were 2 (1 to 24); 7 (1-24); 2 (1-3). Thirty-three reasons emerged, related to four broader categories. "Vicarious thinking," including responding to others' scores, was the most frequently coded reason overall (23%; 24%; 21%) and per participant (42%; 45%; 41%) followed by time to reflect (14%, 11%, 22% overall; 37%; 27% 43% per participant) and impact on life/functioning (10%; 12%; 4% overall; 21%; 40% 9% per person).

Discussion and Conclusions: The data suggest that seeing other participants' scores facilitates "vicarious thinking," that is, trying to understand the experience of an outcome from the perspective of another, as a main reason for changing score. Time to reflect between rounds, and considering the impact of the outcome on everyday life are other important drivers of score-change.

P32 | Patient participant comprehension of score feedback within a Delphi survey

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Keywords: Core outcome set, Delphi, interview, patient comprehension, patient participation

Background: Delphi studies, used to develop consensus, allow participants to change their responses to a questionnaire after reviewing the summarized responses of other participants. Different methods for presenting feedback within a Delphi are employed in core outcome set (COS) development, including a summary statistic (e.g. median) and histograms. It is not known how well these feedback methods are understood by patient participants. The aim of this small study was to examine patient preferences for style of feedback and to determine whether different feedback methods could be accurately interpreted by patients.

Methods: Participants were patients who had been interviewed for development of the Core outcome research measures in anal cancer (CORMAC) COS for anal cancer (UKCRN Portfolio. 20368). In a separate one-to-one interview, participants completed a simulated 2-round Delphi while being asked to "think out loud". Feedback was presented first as a median then simultaneously as a histogram and pie chart. Participants were asked to explain their understanding of the terms used, for example, "median" and "average" and give an overall preference. Scores for the simulated Delphi were derived from a Delphi for a colorectal cancer COS.

Results: Eight patients were interviewed. No participant understood median; six described average as the mean and two could not accurately explain any average. All participants understood both types of chart, although two required additional explanation of the axes. All valued seeing the spread of scores provided by the charts and the concept of distribution was well understood. Seven out of eight participants preferred the histogram overall.

Discussion and Conclusions: This small study provides the first evidence for patient understanding of methods of feedback within a Delphi. Participants understood and valued seeing the spread of scores as a histogram. Median was not well understood and may be an inappropriate choice for Delphi involving patients. Larger studies are needed to validate these findings.

P33 | Patient-reported outcomes in pregnancy and heart disease: A qualitative study

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Keywords: Heart disease, interview, patient reported outcomes, pregnancy, qualitative

Objective: Patient-reported outcomes are underrepresented in studies on pregnant women with heart disease. Our objective was to conduct focused qualitative research on pregnant women with heart disease with the specific intention of identifying outcomes considered important to them.

Methods: Pregnant patients with a cardiac condition and their family members were recruited from the Special Pregnancy Clinic at Mount Sinai Hospital in Toronto, Canada. Upon consenting to participate in the study, semistructured interviews with an emphasis on eliciting outcomes were undertaken with patients and family members. Interviews were conducted until saturation was reached and no new outcomes were identified. Thematic analysis was performed to identify themes important to participants. These were grouped based on a previously published taxonomy.

Results: Sixteen participants (13 pregnant women and three partners) were recruited and completed the interviews. The mean participant age was 34 $\pm$ 4 years (range 26 to 40) and the mean gestational age 29 weeks $\pm$ 7 weeks (range 16 to 37). The heart conditions included arrhythmias ($n = 5$), complex congenital ($n = 5$), and valvular heart disease ($n = 3$). Themes that arose from interviews with pregnant women included hospital visits and resource allocation, mental health, communication among healthcare providers, and concern of a congenital malformation in their baby. Family members' supported the concerns of their pregnant partners, but emphasized in addition prioritizing maternal health while making trade-offs between maternal and fetal health.

Conclusion: These interviews provide unique insight into the experiences of women with heart disease and their family members with regard to pregnancy. Despite the diversity in the women's cardiac conditions, common outcomes were identified as important in all interviews. Most of these were not represented in published studies. A core outcome set incorporating these patient-reported outcomes is currently being developed.

P34 | Enablers and barriers for implementing a COS for pulmonary rehabilitation in people with COPD—health professionals' perspectives

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Keywords: Chronic obstructive pulmonary disease, core outcome set, pulmonary rehabilitation

Patients with chronic obstructive pulmonary disease (COPD) have limited access to pulmonary rehabilitation (PR) despite being a fundamental intervention for their management. Potential of improvement has been used for prioritization; however the response to PR depends on the outcomes used to assess these patients. Currently, there is no core outcome set (COS) for PR. Health professionals are key-stakeholders with an important role on selecting outcomes and implementing PR. However, their views on the enablers/barriers to achieve a successful COS have never been explored. Thus, this study explored health professionals' views on the potential enablers/barriers for implementing a COS for PR in patients with COPD. Semi-structured interviews were conducted with 10 health professionals (two medical doctors, six physiotherapists, and two nurses, $n = 2$ 20% male, 40.7 ± 14.3 years old, 6.7 ± 9.7 years of experience). Data were analyzed with thematic analysis. Three themes were interpreted. A COS should be: (1) quick, simple, and meaningful; (2) credible and reliable; and (3) free and global. Perceived enablers were having a COS easy to understand by patients and health professionals, which translates the results "that you can see" and is adjustable to each patient; that received inputs from patients' organizations and recognized societies from different countries to ensure credibility, is available to all community through platforms and social media, and is composed by instruments with strong clinimetric properties. Potential barriers were having a long list of outcomes with time-consuming instruments, outcomes only pertinent for specific contexts, and having charges related to the COS, namely with instruments. However, health professionals felt that overcoming those barriers would allow comparing different programs and grow the investment in effective PR. Although this COS was perceived as challenging by health professionals, it was also recognized as a crucial step to improve the quality of care and change national and international policies regarding PR.

P35 | Improving core outcome set development for children and young people: Learning from a case study in acute appendicitis and consultation with an international group of children and young people

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Keywords: Acute appendicitis, children, core outcome set, young people participation

Researchers are increasingly including patients in studies to agree which outcomes to measure in research. However, few published core outcome set (COS) studies have included children and young people (CYP) and parents as participants and there is currently no guidance on optimizing COS methods to engage CYP and parents. We aimed to better understand barriers and facilitators to CYP and parents participating in COS studies and case study of CYP and parent participation in the development of a COS for CYP with acute appendicitis. Following this, we sought the perspectives of 70 CYP (aged between 10 and 18 years old) on COS methods during two workshops at the International Children's Advisory Network (iCAN) Research and Advocacy Summit. Fewer CYP (n = 3/15, 20%) completed all three Delphi phases for the acute appendicitis COS, compared with parents (n = 32/67, 48%) and surgeons (n = 55/115, 48%). Our original intention to have all three stakeholder groups together for a single consensus meeting proved infeasible. Parents felt a central England location and request to attend all day was impractical. CYP at the iCAN Summit suggested that COS methods for CYP should be more appealing and interactive, and that Delphi surveys should have fewer outcomes, be less wordy, and use audio-visuals to be more engaging. CYP thought it was important to offer incentives but they advised that feeling valued and knowing how COSs improve research and treatments would also encourage participation. We encountered challenges in recruiting and retaining CYP and parents in the development of a COS for CYP with acute appendicitis and were impeded by a lack of guidance on optimal methods. The perspectives of CYP and parents provide pointers to guide COS development in pediatrics. However, further work is needed to optimize COS methods and accessibility for CYP and parents to ensure that COSs are meaningful and relevant to them.

P36 | Core outcome sets for rare inherited metabolic diseases to support registry-based randomized trials: Systematic review findings

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Keywords: Clinical trials, core outcome set, rare inherited metabolic disease, registries, systematic review

Purpose: There are important evidence gaps related to the effectiveness of therapies for rare inherited metabolic diseases (IMD) in children. Registry-based randomized trials are a promising strategy for addressing these gaps; they need to incorporate standardized collection of outcomes that are meaningful to patients and families, health care providers, and health systems. In the first phase of a project to establish core outcome sets (COS) for each of two relatively common IMD, phenylketonuria (PKU) and medium-chain acyl-CoA dehydrogenase (MCAD) deficiency, we identified outcomes described in previously published studies.

Methods: Following development and implementation of a peer-reviewed search strategy, two reviewers independently screened retrieved citations for eligibility. We extracted outcomes from the reviewed studies and classified unique outcomes under domains within five a priori defined core areas: pathophysiological manifestations, growth and development, resource use, life impact, and death.

Results: We identified 382 articles for inclusion in the review, 345 of which described outcomes for PKU and 51 for MCAD deficiency. For PKU and MCAD deficiency, respectively, we identified 97 and 83 unique outcomes within 11 and 10 domains. Studies described a median of 3 (PKU) or 4 (MCAD deficiency) unique outcomes, most frequently within the core area of pathophysiological manifestations (PKU: $n = 286$ studies; MCAD deficiency: $n = 30$ studies). The most frequently described outcomes were blood phenylalanine ($n = 232$ studies), cognition/intelligence ($n = 83$), and energy metabolism ($n = 50$) for PKU; and death ($n = 25$ studies), hospitalization ($n = 16$), and cognition/intelligence ($n = 15$) for MCAD deficiency.

Conclusions: There was substantial heterogeneity across studies of PKU and MCAD deficiency with respect to the outcomes they incorporated. Studies were more likely to describe pathophysiological outcomes relative to more patient-centered outcomes. A COS for each condition will be instrumental in supporting useful registry-based randomized trials that generate meaningful evidence to guide treatment of these rare diseases.

P37 | Use of core outcome sets: NICE guidelines, surveillance reviews, and quality standards

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Keywords: Core outcome set implementation, guidelines, quality standards, surveillance reviews

Background: The difficulties caused by heterogeneity in outcome measurement are well known to those involved in synthesizing evidence to inform decision making. To address this issue, various initiatives have been established to promote the development and use of core outcome sets (COS) in clinical trials, health technology assessments, systematic reviews, and clinical guidelines. The National Institute for Health and Care Excellence (NICE) produces guidelines and quality standards for the UK's National Health Service and the public health and social care sectors. To improve the quality of its guidelines and quality standards, NICE actively encourages the use of COS during development.

NICE Guidelines: NICE encourages the use of relevant, high-quality COS to inform the development of guidelines in clinical, public health, and social care areas. In the 2018, draft of Developing NICE guidelines: the manual 3 (to be published in January 2019), the use of COS, and COMET database are formally endorsed, where suitable and appropriate, during the development of guideline scope and guideline review protocols.

There are also ongoing methods project within the guidelines program:

- COS for asthma management: consensus project between NICE, Cochrane Airways, and the COMET Initiative. The objective is to reach consensus on a core outcome set for asthma management across the three organizations.
- Exploring the use of core outcome sets in public health and social care research and evidence-based decision-making. The objectives are (i) to map existing COS work in public health and social care; (ii) to raise awareness; (iii) to explore the barriers and facilitators to use of COS; and (iv) methodological issues in the development of COS for public health and social care.

NICE Surveillance reviews: NICE also has a guideline surveillance program that reviews new evidence after guidelines are published, to decide whether an update is needed. New evidence on COS is considered to be one of the key indicators for update. Current informal processes for identifying outcomes during surveillance bring up a lot of outcomes that may be "unimportant," but which are still used when deciding whether to update a guideline.

An exploratory research to investigate how outcomes in surveillance are currently considered was carried out, with the consideration of the need to create a more formal process in the future. Preliminary results from this exploratory research found that there are a lot of outcomes not included in COS and original guidelines that are being identified in surveillance evidence summaries. This suggests that a high number of potentially "unimportant" outcomes are being identified in surveillance. Therefore, there is reason to create a more formal process for outcome assessment in surveillance of NICE guidelines

NICE Quality standards: NICE quality standards identify priority areas for quality improvement in a defined area, with almost all being underpinned by NICE guidance. There are two main components to a quality standard: the action-focused quality statements and the measures associated with them. The statements specify and describe the area for quality improvement, and the measures can be used to assess the quality of care or service provision. The quality standards always include the identification of outcomes attributable to individual statements and "overarching outcomes" that the standard will contribute to.

To ensure the outcomes included in NICE quality standards align to the underpinning evidence and support measurement so users can assess changes in outcomes, moving forward, outcomes included in quality standards will be based on existing COS when possible, reflecting the approach set out in the draft 2018 update to Developing NICE guidelines: the manual.

More formal use of COS will be considered further when the quality standards process guide is next updated (ongoing).

P38 | Assessing harmonizing outcome measures for eczema (HOME) Core outcome set and instrument uptake using the WHO international clinical trials registry platform

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Keywords: Atopic Dermatitis, core outcome set, Eczema, uptake

Background: In 2011, the HOME (Harmonizing Outcome Measures for Eczema) initiative recommended four core outcome domains be captured in all eczema trials (clinician-reported signs, patient-reported symptoms, quality of life, and long-term control). The agreed core outcome measurement instruments for signs and symptoms are Eczema Area and Severity Index and Patient Oriented Eczema Measure, respectively. Here, we assess HOME core outcome set (COS) uptake using an adaptation of the methods used for assessing the uptake of the rheumatoid arthritis COS.

Methods: All interventional studies of eczema/atopic dermatitis (AD) treatments captured in the World Health Organization (WHO) International Clinical Trials Registry Platform were identified. Outcome and instrument data were extracted from the trial registry entries. The main uptake measure was the percentage of trials that planned to measure data on the HOME COS based on the outcomes listed in the trial registry. The percentage of studies planning on using the agreed core measurement instruments was also calculated.

Results: We identified 241 studies assessing eczema/AD treatments in the WHO Platform between January 2005 and June 2018, of which 174 were within the scope of the HOME COS. Data extraction is currently ongoing and the results will be presented at the COMET VII meeting.

Conclusions: Assessing COS uptake allows the impact of research on the development of COS to be assessed. This is the second-known evaluation of COS uptake using trial registries, and the first to utilize the WHO platform that provides a single point of access to clinical trial information across a broad spectrum of individual registries.