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PREgnancy Nutrition: A protocol for the development of a Core Outcome Set (PRENCOS)

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Abstract

Objective: To develop a Core Outcome Set (COS) for pregnancy nutrition research that is relevant to varied stakeholders and resource settings.

Methods: This study has three distinct phases. The first phase involves generating a list of outcomes for consideration for the COS. This includes a systematic review of studies evaluating nutrition during pregnancy where all outcomes reported in relevant literature will be extracted. Qualitative interviews with currently or previously pregnant women will also be conducted. This step will supplement the findings of the systematic review by identifying additional outcomes of importance to this stakeholder group. In the second phase of the study, healthcare professionals, researchers, and mothers from various international resource settings will be invited to participate in a two-round modified Delphi survey. The aim of the survey is to gain consensus on which outcomes are most important to include in the COS. Finally, a face–face consensus meeting will be held with a select group of participants to finalize the COS.

Conclusion: This COS will support standardization of outcome reporting in pregnancy nutrition research and ensure that selected outcomes are considered important by a variety of stakeholders. This will enhance the evidence behind nutrition interventions in pregnancy to improve outcomes for pregnant women.

KEYWORDS

Core Outcome Set; Diet; Maternal health; Nutrition; Outcomes; Pregnancy

1 | INTRODUCTION

Maternal nutrition during pregnancy can affect maternal health during pregnancy and beyond.[1] It also influences the intrauterine environment of the developing fetus and this may influence the health and development of children in utero right through to adulthood.[2–6] Therefore, nutrition during pregnancy is an important consideration in the management of pregnant women and in the overall life course approach to health care and health promotion. While numerous trials have evaluated the effect of dietary interventions in pregnancy, outcome selection and reporting within these studies is largely inconsistent. A recent systematic review of diet and lifestyle interventions in pregnancy identified 142 different outcomes and over half (51%) of those appeared only once.[7] This is a barrier to the generation of high-quality evidence as it limits our ability to compare findings from individual studies in systematic reviews, which leads to significant research waste. In addition, outcome selection and reporting in research studies has the potential to influence clinical practice, research methods, and the utilization of resources.[8] This makes outcome selection and reporting of critical importance within scientific research.

A Core Outcome Set (COS) is a set of outcomes that are considered essential to report within a specific area of research.[9] Once defined, the expectation is that these outcomes will be measured and reported in all relevant research studies. However, researchers will

have the option to report on additional outcomes depending on their research questions. Recognizing the current inconsistency in outcome reporting within maternal and newborn medicine, over 80 editors of women's health journals formed a consortium and launched the Core Outcomes in Women and Newborn health initiative (CROWN) (www.crown-initiative.org). Their aim is to support the development, dissemination, and use of COSs in maternal health research. In addition to facilitating the comparison and amalgamation of results from individual studies, COSs have the potential to reduce reporting bias within scientific research and therefore improve study quality.[10] At present there is no COS focused specifically on nutrition in pregnancy. Therefore, the aim of the present study is to develop such a COS for use in studies that evaluate nutrition during pregnancy. This protocol details a comprehensive overview of the process for developing a COS for pregnancy nutrition research.

2 | METHODS

This study protocol was registered prospectively in the Core Outcome Measures in Effectiveness Trials (COMET) database (COMET) (http://www.comet-initiative.org/studies/details/1273). While there is no standard method for the development of a COS, the study design follows the COMET handbook and COS-STAD (minimum STAndards for Development of Core Outcome Sets) and will involve three distinct phases (Fig. 1).[8,11] The study design was also informed by previously published COS study protocols.[12–16] The first phase will involve generating, through a systematic review and qualitative interviews, a long list of outcomes that will be considered for inclusion in the COS. Qualitative interviews will be limited to current or prospective mothers only as it is assumed that the opinions of healthcare professionals and researchers are sufficiently captured in scientific literature. In addition, including the opinion of patients in COS development is recommended by COMET.[8] The second phase will involve a modified Delphi survey including a variety of international stakeholders. The aim of this phase is to refine the long list of outcomes from phase 1 and identify a list of outcomes for inclusion in the COS. The third and final phase involves a meeting where outcomes for which consensus could not be reached will be discussed. Ethical approval was provided from the National Maternity Hospital and the study will be completed in line with the Declaration of Helsinki.

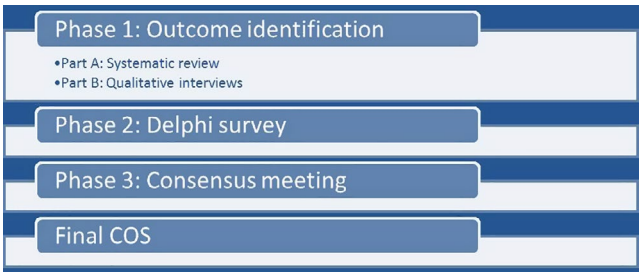

FIGURE 1 Study design overview.

2.1 | Phase 1: Outcome identification

2.1.1 | Part A: Systematic review

Studies evaluating the effect of maternal nutrition interventions or exposures during pregnancy will be systematically reviewed. The full protocol including the search strategy will be available online via the PROSPERO database and the review will be reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[17] This systematic review will be completed in line with previous systematic reviews which informed COS development.[15,16,18]

2.1.1.1 | Search strategy

Major electronic databases will be searched, including PubMed, Embase, CINAHL, clinicaltrials.gov, and the Cochrane Library, for studies on nutrition interventions and exposures in pregnancy. Adaptations to the search strategy will be made for each database and records categorized as "in progress" or E-pub ahead of print will be included. The reference list of relevant studies will also be hand-searched to identify additional publications for inclusion that were not picked up in the original search. Records from each database will be combined and duplicates removed.

2.1.1.2 | Identification of eligible studies

The primary research question is "What outcomes have been reported in studies evaluating the effect of maternal diet or nutrition during pregnancy?" Studies will be eligible for inclusion if they involve an intervention during pregnancy which aims to result in changes in dietary and/or macronutrient intakes (e.g. dietary advice, supplementation, or behavioral change), or involve observations between dietary indices (e.g. food intakes, diet quality, macronutrient intake) and outcomes. This can be with pregnant women of any age, any gestation, and conducted in any setting. Multicomponent interventions where diet is combined with another lifestyle or physical activity intervention will also be included. Studies that involve single- or multi-micronutrient interventions or observations only will not be included. Therefore, studies will be eligible for inclusion if they are trials, whether randomized, quasi-randomized, or non-randomized, cohort studies, or cross-sectional studies. There will be no date restriction. Systematic reviews will also be included to identify any potential newly generated composite outcomes. However, individual outcomes identified within the systematic reviews will not be extracted. Case reports, case series, case-control studies, commentaries, letters to the editor, narrative reviews, expert opinions, and articles written in a language other than English will be excluded.

Two reviewers will independently screen titles and abstracts of identified studies. Any discrepancies from this initial assessment will be resolved by involving a third reviewer and, if necessary, discussion with the wider research team. Studies will be classified as potentially eligible, ineligible, and unclear. The full text of unclear and potentially eligible studies will be obtained and independently assessed for inclusion by two reviewers. Any studies excluded at this stage will have the exclusion reason documented. Records will be managed using Mendeley.

2.1.1.3 | Data extraction

Two independent reviewers will extract outcomes (including primary, secondary, and composite outcomes) from eligible studies verbatim from the literature, using a data extraction tool.[8] Data on study characteristics will be recorded such as author details, study population, study type, nature of nutrition intervention or exposure, sample size, location of study, and date of publication.[15] The definition of each outcome, location of outcome reporting within the paper, and the chosen method for outcome measurement will also be collected. As the aim of this review is to identify a long list of outcomes for consideration for inclusion in the COS, risk of bias in studies will not be assessed. This is acceptable based on suggested COS development methodology.[8] The authors of the study will be contacted in the case of missing or unclear information. The study outcomes will be categorized based on the taxonomy of the COMET initiative.[11,19] Any disagreement in categorizing the identified outcomes will be resolved by involving a third reviewer. Outcomes that are clinically similar will be combined to refine the initial outcome list and simplify the consensus process. This is based on recent evidence that having higher numbers of items within a Delphi consensus survey is associated with significantly lower response rates.[20]

2.1.1.4 | Data analysis

The systematic review results will be reported in accordance with PRISMA guidelines.[17] The characteristics of the study will be narratively described and findings will be presented in texts and tables with the reporting frequency of each outcome. High heterogeneity in the outcomes reported is expected based on previous reviews; hence, outcomes will be reported as a list with frequencies.

2.1.1.5 | Outcome definitions

Once a preliminary list of outcomes is identified and characterized through the systematic review, lay definitions for each outcome will be developed that will be piloted in our qualitative interviews.[8]

2.1.2 | Part B: Qualitative interviews

This part of the outcome generation phase will determine which outcomes pregnant women and mothers think are important for inclusion in the COS. This is an important step as the opinion of these stakeholders may be under-represented in scientific literature.[9] A sample size of n=30 will be considered sufficient to achieve data saturation and to ensure that adequate and quality data are collected to provide a detailed understanding of the priorities and opinions among this group. This sample size has been used in previous COS development studies.[15] To ensure a global perspective, an aim of the present study is to include pregnant women from LMICs.

2.1.2.1 | Participants

Women will be recruited through the outpatient department of the National Maternity Hospital in Dublin and women from a broad range of demographics will be purposively recruited. This recruitment will be supplemented with additional methods used previously for this stakeholder group which will include social media, online pregnancy and parent forums, and with national and international advocacy groups and organizations such as healthcare professional bodies (e.g. Irish Nutrition and Dietetic Institute, International Federation of Gynecology and Obstetrics [FIGO]).[13] Women will be eligible to participate if they have an adequate level of oral English or the availability of an interpreter. The location of each participant interview will be documented and be reported by country. At the time of recruitment, informed consent will be obtained and information such as gestational age (where relevant), parity, co-morbidities, and demographics will be requested before commencing the interviews.

2.1.2.2 | Qualitative interview structure

Qualitative interviews will be conducted in person or via telephone. After providing some background to the study, women will be asked to list all of the outcomes they think are important to measure and report in a study examining nutrition in pregnancy. Once the participant has exhausted their spontaneously generated outcomes, the outcome list from the systematic review will be presented in the Delphi survey format, along with the suggested lay definitions (this will be read out to participants during telephone interviews). Where feasible, an example of a Delphi survey will also be piloted with the women and through a "think aloud" process, participants will be asked to explain verbally their thoughts on all aspects including comprehensibility, usability, and clarity. Finally, women will be shown an example of the proposed feedback form that is expected to be produced between rounds in the Delphi survey. The aim of this is to ensure comprehension by this stakeholder group before commencing the Delphi survey.[8]

2.1.2.3 | Data synthesis and analysis

Both in-person and telephone interviews will be digitally recorded and transcribed for qualitative data analysis. At this stage, all data will be anonymized. All transcripts will be analyzed by a single researcher and a second researcher will independently analyze 10% of transcripts to ensure agreement. Any differences in coding will be resolved by consensus.[16] Any novel outcomes will be recorded and categorized following the taxonomy used for part A in the systematic review.

2.1.2.4 | Refinement of outcome definitions

Interview feedback on the outcome definitions will be analyzed. Where necessary and appropriate, the specific language used by the women will be incorporated into the lay explanations to enhance their applicability to Delphi survey participants.[8]

2.2 | Phase 2: Delphi survey

A modified Delphi survey will be conducted with representatives from all relevant stakeholder groups internationally.[8] This is an iterative consensus process during which participants will be asked to rank how important they think outcomes are to include in the final COS. In this survey, participants will be provided with the full list of outcomes refined from phase 1 and ask them to rank each of these outcomes on how important they are to include in the COS. Clear

guidance will be provided on the distinction between a "key data point," necessary to interpret the effect of an intervention/exposure, and an "outcome," which provides an indicator of the intervention/exposure effect.

2.2.1 | Study participants

As has been done in other COS development studies, three distinct groups of stakeholders will be included in the Delphi survey.[13] These include currently or previously pregnant women and mothers, medical and other healthcare professionals involved in the care of pregnant women, and researchers with an interest and expertise in studying pregnant women and/or nutrition. Typical recruitment strategies will be followed for each stakeholder group which have been used previously in COS development studies.[13,16] Women will be recruited as per part B's qualitative interviews and recruitment fora will include pregnancy healthcare settings, parenting forums/groups, and social media. Clinicians will be recruited through national and international societies/professional associations. These will include obstetricians, gynecologists, general practitioners, midwives, public health nurses, and allied health professionals such as dietitians. All clinicians and relevant healthcare professionals will have significant experience working with pregnant women. Researchers will include those with an interest and experience in pregnancy. They will be recruited through the author lists of included studies in the systematic review as well as use of outreach with international research organizations/networks. Snowball sampling will be encouraged.[21]

As the information about and link to the Delphi survey will be circulated via email, the email addresses of any potential participants will be requested for this purpose. Participants will be invited from a variety of backgrounds and include representatives from Canada, the USA, Europe, Africa, and Asia-Pacific. The aim is to have a comprehensive spread of international participants so that the perspectives of individuals from or working in different practice settings with varying resources can be incorporated. Where necessary, interested parties will also be asked to recommend additional colleagues or peers to take part to ensure participation is broad, inclusive, and comprehensive. A minimum of 20 participants will be included within each stakeholder group for the first round of the Delphi survey. This number is in line with the sample sizes used in similar COS development studies and should be sufficient to gain a wide range of views while also maximizing response rate.[8,12,13]

2.2.2 | Communication with participants

In the initial email invitation, stakeholder-specific information will be included outlining the project background, the Delphi purpose and process, and the potential impact of their participation on nutrition research within this population group.[6] The survey will be disseminated using DelphiManager™ software (developed by the COMET initiative).[8,11,22] Participants will be required to register with DelphiManager™ before being able to complete the survey, at which time consent for participation will be obtained and demographic information collected.

2.2.3 | Delphi survey structure

The Delphi survey consists of two rounds and all items from the first round will be retained in the second. Consensus is not necessary for all outcomes as the purpose of the survey is to define which outcomes are essential for COS inclusion.[8] Any outcomes without consensus after the survey's second round will be discussed at the consensus meeting. All survey data will anonymized and only the local core study team will have access to the full list of Delphi survey participants.

2.2.3.1 | Round one

The first round of the Delphi survey will be closed-ended (modified Delphi survey).[8] Participants will be provided with the full list of outcomes for consideration and asked to rank the importance of including each outcome in the final COS using a 9-point Likert scale as recommended by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group.[23] As has been done previously, scores of 1–3 will be considered "not essential" for inclusion, scores of 4–6 "important but not critical" for inclusion, and scores of 7–9 "critically important for inclusion." Participants will also be given the opportunity to select "unable to score" where appropriate.[8,12,13,16] Beside each outcome, there will be an option to provide free text to justify answers provided but this will not be mandatory. A single open-ended question will be provided at the end of the first-round of the survey. This can be used by stakeholders to provide any additional outcomes they think should be considered for inclusion but were not identified through phase 1 of the study.[8] Any new outcome will be categorized, discussed within the core research team, and, if appropriate, will be brought forward to round two of the survey.

2.2.3.2 | Round two

In the second and final round of the survey, each participant will be provided with their scores for each outcome and the collated scores for each stakeholder group. Based on this, participants will have the opportunity to change their scoring for each outcome or retain their original score. Participants will also be asked to rank any newly identified outcomes.

2.2.4 | Data analysis and inter-round feedback

Descriptive statistics will be generated after each round based on the different stakeholder groups involved in the Delphi survey. The number of participants scoring each outcome will be identified and distribution of scores stratified by stakeholder type. In round two of the survey, each participant will be provided with their round one score for each outcome and the mean or median for each of the stakeholder groups. Participants will be blinded to the other participants and their individual scores.

2.2.5 | Consensus

Consensus levels will be set a priori based on commonly used definitions in the development of COS.[8,12–14] "Consensus in" will be defined as at least 70% of each stakeholder group participants score the outcome as "critically important for inclusion" and less than or equal to 15% of participants score it as "not essential." The level for excluding an outcome from the final COS will be defined as at least 70% of each stakeholder group participants score it as "not essential" and no more than 15% of participants score it as "critically important for inclusion".[8] Outcomes that fail to meet either of these conditions will be considered to have reached no consensus and will be brought forward to the consensus meeting.

2.2.6 | Minimizing attrition

Non-responders will be pre-defined as those who do not complete the Delphi first round despite two email reminders, each of which will be 2 weeks apart. For those who complete round one of the survey, a response rate of 80% or greater for each stakeholder group will be deemed acceptable.[12] This level has been previously set in other COS development studies.[16] Dropouts will be classified as those who complete the survey's first round within the initial 6-week period but fail to complete the second round within the same timeframe despite three reminder emails.[8,16,24] Participants who do not complete the first round of the survey will not be invited to the second round. Where possible, we will try to align the timing of the Delphi survey to relevant international meetings, conferences, and congresses with the aim of improving response rates and speed of the project.[25]

2.3 | Phase 3: Consensus meeting

The third and final phase of this study is the consensus meeting. Participants will be selected from those who completed both rounds of the Delphi survey. A pragmatic approach will be taken on the numbers attending based on the location and timing of the meeting.[8] Attendees will provide consent via email before the meeting.

2.3.1 | Meeting structure

The meeting will be a guided discussion with the Delphi survey results presented initially and through nominal group technique, stakeholder opinions will be collected and organized. The focus of the meeting will be on the outcomes for which consensus was not reached. All attendees will be sent a reminder of the Delphi survey results, including their individual scores for each outcome and the average score of each stakeholder group, before the meeting. Once the results have been reviewed, participants will be asked to vote anonymously for the outcomes that should be included in the final COS. If there are any remaining outliers, they will be reviewed through further discussion applying nominal group technique until consensus is reached.

3 | PROTOCOL ADJUSTMENTS

Further modifications to this protocol will occur if changes are required to facilitate the consensus process. For example, participants in the Delphi survey may identify critical issues that need to be amended in subsequent rounds to maximize the response rate or additional steps may need to be included to ensure full stakeholder representation.[7] Any adjustments will be added to the COMET protocol and be described in any future publications.

4 | DISCUSSION AND IMPLEMENTATION OF THE COS

Despite CROWN's launch, there are still fewer than 10 published COSs in the area of pregnancy and childbirth and the methods used to create them vary.[26] This study intends to reach international consensus on the most critical outcomes to include in nutrition research in pregnancy from a variety of stakeholders. This will help increase public representation in outcome selection and reduce outcome reporting bias and heterogeneity in relevant research studies; all of which will support high-quality evidence synthesis to inform practice and international nutrition guidelines and policies. The Delphi survey will be used to generate consensus within the study groups as it can be completed anonymously and independently by the participant, in their own time and online. This will avoid certain biases associated with face-to-face meetings such as the effect of dominant individuals on the opinions of others. The modified Delphi survey was chosen to limit the number of rounds that the participant is required to complete so that study participation burden is limited. In addition, the Delphi survey has the potential to have wide geographical reach that would otherwise not be possible with in-person meetings. This is important to enhance the international relevance of the final COS and ensure that the minimum outcomes selected are generally applicable across a variety of research and practice settings and applicable regardless of the variance in resources available and health system structures.

The results of this systematic review will build on Rogozińska's review in 2017[7] and may identify additional outcomes through the inclusion of a broader range of eligible study designs. The systematic review and final COS will be published and disseminated at international obstetrics and nutrition meetings. The dissemination will support the advancement of nutrition research in pregnancy and inform future COS development and implementation of this COS into practice. Archiving of the results will also occur within the COMET and CROWN databases. A COS for pregnancy nutrition will help streamline outcome reporting within nutrition research in pregnancy so that high-quality evidence on the most critical outcomes can be generated through systematic reviews. In addition, identifying key data that should be reported in studies evaluating nutrition in pregnancy will support the enhancement of the quality of literature in this area. This will strengthen the evidence base for nutritional recommendations in

pregnancy and aid in the advancement of nutritional care of pregnant women worldwide.

AUTHOR CONTRIBUTIONS

All authors were involved in the conception and design of the study. SLK wrote the manuscript. SLK, EOB, SOR, and FMcA designed the conceptual framework with input from all other authors. All authors provided input into the study design, analytical methods, and revisions of the manuscript.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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