Methodological decisions influence the identification of potential core outcomes in pre-eclampsia related studies: a sensitivity analysis informing the development of guidelines for future core outcome set developers

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Running title
Developing a long list of potential core outcomes

Abstract

Objective

To quantify the effect of different methodological decisions on the identification of potential core outcomes to inform the development of recommendations.

Design

Mixed methods study.

Setting

A core outcome set for pre-eclampsia was used as an exemplar.

Sample

A long list of potential core outcomes was developed by undertaking a systematic review of pre-eclampsia trials and performing a thematic analysis of in-depth patient interviews.

Methods

Specific methods used to generate long lists of potential core outcomes were evaluated, including limitations placed within the search strategy and varied approaches in the extraction of outcomes from published trial reports.

Results

Different methodological decisions had a substantial impact on the identification of potential core outcomes. Extracting outcomes from published pre-eclampsia trials was an effective way of identifying 48 maternal, eight fetal, 25 neonatal outcomes, and eight patient-reported outcomes. Limiting the extraction of outcomes to primary outcomes or outcomes commonly reported in pre-eclampsia trials reduced the number and diversity of potential core outcomes identified. Thematic analysis of in-depth patient interviews ensured an additional five patient reported outcomes and six outcomes related to future child health were identified.

Conclusions

Future core outcome set developers should use quantitative and qualitative methods when developing a long list of potential core outcomes.

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Keywords

Core outcome sets; outcomes; pre-eclampsia; qualitative interviews; and systematic review.

Tweetable abstract

@OfficialNIHR research published in @BJOGtweets informs new recommendations for future @coreoutcomes developers

Introduction

Clinical research should ultimately improve patient care.[1] The ability of randomised controlled trials to inform clinical practice can be limited by several issues including the failure to consider the perspectives of patients when selecting outcomes, variations in outcome measures, and outcome reporting bias.[2, 3] Problems with poor outcome selection, measurement, and reporting can be addressed by developing core outcome sets to standardise outcome selection, collection, and reporting across a specific disease area.[4, 5] Over sixty core outcome sets are being developed across ours speciality, including twin-twin transfusion syndrome, selective fetal growth restriction, and neonatal medicine.[6-11]

Core outcome sets are developed in three stages (Figure 1).[12] The first step is to develop a long list of potential core outcomes by undertaking a systematic review of published randomised controlled trials. A minority of core outcome set studies have also used qualitative methods, for example in-depth patient interviews.[12] The next step is to reduce the long list of potential core outcomes to a core outcome set using formal consensus methods, including the modified Delphi method. The final step is to determine how the core outcomes should be defined and measured.

As there is considerable uncertainty in core outcome set development methods, we undertook a systematic review of registered, ongoing, and completed core outcome sets relevant to women's and newborn health.[13] When delineating the specific methods used to generate a long list of potential core outcomes, there was considerable variation in the electronic bibliographical databases searched, differences in the limitations placed within the search strategy, including publication date, study size, and study design, and varied approaches in the extraction of outcomes from randomised trial reports. In addition to this heterogeneity in methodology, no examples were found of the use of qualitative research to capture patient views regarding potential core outcomes.

Understanding the most effective methods to use in this emerging field is important in order to reduce waste and unnecessary delays in the outcome set development process and to ensure a comprehensive approach is taken. The objective of this study was to quantify the effect of different methodological decisions on the identification of potential core outcomes to inform the development of specific recommendations for future core outcome set developers. A core outcome set for pre-eclampsia was used as an exemplar.[14]

Methods

The specific range of methods previously used to generate long lists of potential core outcomes were extracted from our systematic review of core outcome set development studies relevant to women's and newborn health.[6] These included differences in the limitations placed within the search strategy, including publication date, study size, and methodological quality, and varied approaches in the extraction of outcomes from randomised trial reports.

The impact of such methodological decisions was then explored using a systematic review of published pre-eclampsia trials and in-depth interviews, previously used for capturing potential core outcomes in pre-eclampsia. Detailed methods have been published elsewhere for each of the two underlying studies.[15-18]

Primary outcomes, secondary outcomes, along with study characteristics, were extracted from the systematic review.[15, 18] Primary outcomes were identified if they were explicitly stated or if an outcome was included in the study's power calculation.[16] Thematic analysis of thirty in-depth interviews with women with lived experience of pre-eclampsia was undertaken identified a further potential core outcome.[17] To facilitate comparisons, both sets of outcomes were organised within a standardised taxonomy (Figure 2).

Specific methodological decisions pertinent to the identification of potential core outcomes were explored in this study, including:

- No limitations placed within the search strategy, inclusion criteria, and all outcomes extracted from published trial reports.
- Limitations placed within the search strategy, including:
    1. Date limitation from 2007 onwards;
    2. Larger trials reporting data from more than 100 participants; and
    3. Trials assessed as higher methodological quality, defined as trials fulfilling the Jadad criteria.[19]
- Different approaches in the extraction of outcomes from study reports, including
    1. Primary outcomes; and
    2. Commonly reported secondary outcomes, defined as a secondary outcome reported in three or more trials.
- Outcomes identified by thematic analysis of in-depth interviews with women with lived experience of pre-eclampsia.

Descriptive tables formally quantified the effect of different methodological decisions on the identification of potential core outcomes (Figure 3).

Patients were not involved in the development of this research study. This is independent research arising from a doctoral fellowship (DRF-2014-07-051) supported by the National Institute for Health Research, awarded following external peer review. The funder had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Results

Seventy-nine pre-eclampsia trials reported 106 different outcomes and thematic analysis of 30 in-depth interviews with women with lived experience of pre-eclampsia identified 71 outcomes (Figure 2). Combining these resulted in one hundred and sixteen unique outcomes organised within a single standardised taxonomy. The impact of seven different methodological decisions were examined across seven outcome domains, including:

- Mortality;
- Maternal outcomes;
- Patient reported outcomes;
- Fetal outcomes;
- Neonatal outcomes;
- Childhood outcomes; and
- Resource utilisation.

Maternal, fetal, neonatal, and childhood mortality

Different methodological decisions had no impact on the identification of maternal, fetal, or neonatal mortality as potential core outcomes (Figure S1). When only primary outcomes were extracted, neonatal and childhood mortality would not have been identified as a potential core outcome.

Maternal outcomes

The methodology used made a substantial difference in the number and diversity of maternal outcomes identified (Figure S2). Considering the results of the systematic review, when no limitations were placed within the search strategy, inclusion criteria, or outcome extraction, 48 maternal outcomes were identified. Limiting the search strategy reduced this to between 15 and 44 outcomes depending on the decision made. Important domains were not captured by some strategies, especially when the search was limited to primary

outcomes (gastrointestinal and neurological morbidity). Thematic analysis of in-depth patient interviews identified 24 maternal outcomes, a single domain, cardiovascular morbidity, was not represented.

Patient reported outcome

Patient reported outcome asses the patients' views of their health states, perceived level of impairment, disability, and health-related quality of life.[20] Considering the results of the systematic review, when no limitations were placed within the search strategy, inclusion criteria, or outcome extraction, five patient-reported outcomes were identified (Figure S3). Limiting the search strategy to larger and higher methodological quality trials did not reduce the number of patient-reported outcomes identified. Thematic analysis of in-depth patient interviews identified five additional patient reported outcomes.

Fetal outcomes

Different methodological decisions resulted in differences in the number of fetal outcomes being identified (Figure S4). Considering the results of the systematic review, when no limitations were placed within the search strategy, inclusion criteria, or outcome extraction, eight fetal outcomes were identified. Limiting the search strategy reduced this to seven outcomes. When only primary outcomes were extracted from trial reports only three fetal outcomes were identified. Thematic analysis of in-depth patient interviews eclampsia identified six fetal outcomes.

Neonatal outcomes

The methodology used made a substantial difference in the number and diversity of neonatal outcomes identified (Figure 4). Considering the results of the systematic review, when no limitations were placed within the search strategy, inclusion criteria, or outcome extraction, 25 neonatal outcomes were identified. Limiting the search strategy reduced this to between 19 and 25 outcomes depending on the decision made. Important domains were not captured

by some strategies, especially when the search was limited to primary outcomes, including neurological morbidity, gastrointestinal morbidity, and infectious morbidity. Thematic analysis of in-depth patient interviews identified 14 neonatal outcomes, three domains, neurological, cardiovascular, and haematological morbidity, was not represented.

Childhood outcomes

The same six neurodevelopmental outcomes were identified when: (1) no limitations were placed within the search strategy, inclusion criteria, or outcome extraction; (2) the inclusion criteria was limited to larger trials; (3) the inclusion criteria was limited to higher methodological quality trial (Figure S5). An additional six outcomes, including growth, disability, and immune system disorders, were identified when in-depth interviews with women with lived experience of pre-eclampsia were thematically analysed.

Resource utilisation outcomes

Considering the results of the systematic review, when no limitations were placed within the search strategy, inclusion criteria, or outcome extraction, four resource utilisation outcomes were identified (Figure S6). Limiting the search strategy did not reduce the number of resource utilisation outcomes identified. When commonly reported outcomes were extracted from trial reports, only two resource utilisation outcomes were identified. When primary outcomes were extracted from trial reports, no recourse utilisation outcomes were identified. Thematic analysis of in-depth patient interviews identified three resource utilisation outcomes.

Discussion

Main findings

This study has demonstrated that different methodological decisions can make a substantial impact on the identification of potential core outcomes. Extracting outcomes from published pre-eclampsia trials was an effective way of identifying a range of maternal, fetal, and neonatal outcomes. However, limitations placed within the search strategy reduced the number and diversity of potential core outcomes identified, particularly for maternal and neonatal outcomes. Limiting the extraction of outcomes to primary outcomes or outcomes commonly reported in pre-eclampsia trials substantially reduced the number and diversity of potential core outcomes identified. Thematic analysis of in-depth interviews with women with lived experience of pre-eclampsia identified an additional 12 (10%) outcomes relating to their own wellbeing and the future health of their offspring. All outcomes will be entered into a Delphi survey to identify a core outcome set for pre-eclampsia.

Strengths and limitations

To our knowledge, this is the first study to objectively quantify the impacts of different methodological decisions on the identification of potential core outcomes. A diverse range of potential core outcomes, identified using quantitative and qualitative research, were successfully organised within a single taxonomy to ensure comparability. Descriptive tables were effective in demonstrating and quantifying the effect of different methodological decisions on the identification of potential core outcomes.

Our empirical evaluation has several limitations. Methodological decisions evaluated within this study were identified by reviewing core outcome set development studies relevant to women's health, applied to pre-eclampsia, and might be different in other topic areas. Further research is required to explore other methodological decisions and to confirm the findings of this study are applicable in other core outcome set development studies

standardising outcomes in other disease areas such as infertility, endometriosis, and preterm birth.[21-23] The study did not evaluate the ease outcome collection, the quality of measurement of the outcome, or other relevant factors. Such an approach could have provided additional insight into the most appropriate methods to identify potential core outcomes. Future core outcome set developers should consider exploring these issues.

Interpretation

Previous core outcome set development studies have rarely discussed the impact of different methodological decisions on the development of a long list of potential core outcomes. An interim study published as part of the development of a core outcome set for preterm birth briefly discussed the potential impact of restricting the search strategy to recently published trials and only extracting primary outcomes from published preterm birth trials. The core outcome set developers noted the number and diversity of outcomes identified "*may have been influenced*" by these decisions.[24] The findings of this study confirms that careful attention should be paid to the development of a long list of potential core outcomes.

The need to develop core outcome sets in women's health to address poorly chosen, collected, and reported outcomes has been demonstrated by several systematic reviews, in a diverse range of conditions including, endometriosis, twin-twin transfusion syndrome, and vaginal and pelvic organ prolapse.[25-29] Unfortunately, there is potential to waste limited resources and introduce unnecessary delays in identifying a useful core outcome sets if inappropriate development methods are used. There is currently limited guidance regarding the development of a long list of potential core outcomes and the following specific recommendations for future core outcome set developers are suggested.

Recommendations for future core outcome set developers

Both quantitative and qualitative research methods should be used in developing a long list of potential core outcomes. When undertaking a systematic review of published randomised trials to identify potential core outcomes, no limitations should be placed within the search strategy, inclusion criteria should be broad, and all outcomes should be extracted from trial reports. Restricting the extraction of outcomes from trial reports, including only extracting primary outcomes or commonly reported outcomes, is likely to decrease the number and diversity of potential core identified.

Thematic analysis of in-depth interviews with patients was an effective strategy to ensure relevance to a broad range of stakeholders. It should be noted that less resource intensive data collection methods, including focus groups, observation, and free text questionnaires, secondary analysis of existing data, or meta-synthesis, have not been formally evaluated and could be useful alternative to in-depth interviews. Using qualitative research methods is important as outcomes reported in published research may not hold the same relevance for patients, particularly when published trials pre-dates the recent emphasis on patient and public involvement in study design.

Future core outcome set developers should carefully consider and draw upon the expertise of a range of stakeholders when considering different methods to identify a robust set of potential core outcomes. The specific methods, justification for their selection, and their potential impact on the final core outcome set should be explicitly discussed within interim publications and the final core outcome set publication. This approach should increase transparency, improve clarity, and reduce bias.

Given the uncertainty in core outcome set development methods, further methodological research is required. A research agenda should be embedded within future core outcome set development studies to address this uncertainty and strengthen the evidence base.

Priority should be given to the evaluation of development methods which have the potential to minimise bias, maximise efficiency, and increase implementation. Further research is needed to understand the relationship between potential core outcomes entered into a consensus development method and the core outcomes eventually identified. Is a comprehensive long list of potential core outcomes required to secure a final core outcome set relevant to key stakeholders? The modified Delphi method is commonly used to identify consensus 'core' outcomes and enables participants to suggest additional outcomes to be entered into the consensus development process. What is not known is whether outcomes suggested by participants within the consensus development process could address perceived deficiencies in the methods used to develop a long list of potential core outcomes or even making certain methods redundant.

Conclusion

Different methodological decisions have considerable impact on the number and diversity of potential core outcomes identified. When designing a systematic review to identify potential core outcomes, future core outcome set developers should use an extensive search strategy, pursue a broad inclusion criterion, and extract all outcomes from published trial reports. Qualitative research has an important role in ensuring the long list of potential core outcomes holds sufficient relevance to patients. Future core outcome set developers should implement this study's recommendations to ensure comprehensive ascertainment of potential core outcomes.

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Conflicts of interest

Prof Richard J. McManus has received blood pressure monitors for research from Omron. The remaining authors no conflict of interests.

Author contributions

Study concept and design: JMD, SZ, and RMcM. Acquisition of data: JMD, MH, SZ, and RMcM. Analysis and interpretation of data: JMD, MH, SZ, and RMcM. Drafting of the manuscript: JMD, SZ, and RMcM. Critical revision of the manuscript for important intellectual content: MH. Obtaining funding: JMD, SZ, and RMcM. Study supervision: SZ, and RMcM.

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Ethical approval

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