A core outcome set for future endometriosis research: an international consensus development study


Objective To develop a core outcome set for endometriosis.

Design Consensus development study.

Setting International.

Population One hundred and sixteen healthcare professionals, 31 researchers, and 206 patient representatives.

Methods Modified Delphi method and modified nominal group technique.

Results The final core outcome set includes three core outcomes for trials evaluating potential treatments for pain and other symptoms associated with endometriosis: overall pain; improvement in the most troublesome symptom; and quality of life. In addition, eight core outcomes for trials evaluating potential treatments for infertility associated with endometriosis were identified: viable intrauterine pregnancy confirmed by ultrasound; pregnancy loss, including ectopic pregnancy, miscarriage, stillbirth, and termination of pregnancy; live birth; time to pregnancy leading to live birth; gestational age at delivery; birthweight; neonatal mortality; and major congenital abnormalities. Two core outcomes applicable to all trials were also identified: adverse events and patient satisfaction with treatment.

Conclusions Using robust consensus science methods, healthcare professionals, researchers, and women with endometriosis have developed a core outcome set to standardise outcome selection, collection, and reporting across future randomised controlled trials and systematic reviews evaluating potential treatments for endometriosis.

Keywords Consensus development study, core outcome set, endometriosis, modified Delphi method, modified nominal group technique.

Tweetable abstract @coreoutcomes for future #endometriosis research have been developed @jamesmnduffy.

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†endo:outcomes group members are listed in Appendix 1.

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Introduction

Endometriosis research should inform clinical practice and in doing so improve the treatment outcomes of women with endometriosis. For this to be possible, randomised trials should select, collect, and report outcomes that reflect the realities of everyday clinical practice and are relevant to women with endometriosis.\(^1\)\(^2\) Unfortunately, many endometriosis trials fall short in this regard. For example, when considering randomised trials evaluating potential surgical treatments for infertility associated with endometriosis, only a minority reported live birth (5/32, 15%), pregnancy loss (7/32, 22%), and adverse events (9/32, 28%).\(^3\) In addition, substantial variation exists in the measurement instruments used to collect individual outcomes. For example, dysmenorrhoea has been measured using ten different measurement instruments, including visual analogue scales, ranked ordinal scales, and symptom questionnaires.\(^5\) Combining different measurement instruments within a meta-analysis is challenging and weakens the reliability of the final summary estimate.\(^6\) Such variation can result in individual researchers reporting outcomes on the basis of statistical significance, which can skew an entire evidence base to overestimate the benefits of treatments and underestimate the harms.\(^1\)

These challenges can be addressed by developing, disseminating, and implementing a minimum data set, termed a core outcome set, to standardise the selection, measurement, and reporting of outcomes across randomised trials and systematic reviews. A core outcome set is developed in three stages. The first stage is to develop a long list of potential core outcomes by undertaking a systematic review of published randomised trials. The next stage is to reduce the long list of potential core outcomes to a core outcome set using formal consensus methods. The final stage is to determine how individual core outcomes should be defined and measured.

Motivated by the desire to improve endometriosis research, an international collaboration supported by the Cochrane Gynaecology and Fertility Group, has brought healthcare professionals, researchers, and women with endometriosis together to develop a core outcome set for future endometriosis research.

Methods

The study was registered prospectively with the Core Outcome Measures in Effectiveness Trials (COMET) initiative (reg. no. 1023). An international steering group, including healthcare professionals, researchers, and patient representatives, was established. A protocol describing the study’s methods has been published.\(^5\)

The core outcome set was developed in a three-stage process using methods advocated by the COMET initiative.\(^6\) Potential core outcomes were identified through a systematic review of previously published endometriosis trials.\(^3\) The long list of potential core outcomes was entered into a modified Delphi method, which facilitated individual stakeholder group convergence towards consensus outcomes. These outcomes were entered into a face-to-face consensus development meeting. Using a modified nominal group technique, consensus outcomes were further prioritised to identify the final core outcome set for endometriosis.

We performed a systematic review of published trials evaluating the potential treatments for endometriosis and extracted the reported outcomes.\(^3\) A comprehensive inventory of outcomes was developed in consultation with the study’s steering group, who were encouraged to remove similar outcomes described using different terminology (e.g. deep vein thrombosis, lower limb thrombosis, pulmonary embolism, embolism, and venous thromboembolism), non-patient-centred outcomes (e.g. inflammatory markers), and outcomes specific to individual experimental interventions (e.g. side effects associated with hormone replacement therapy). Lay definitions were developed for individual outcomes in consultation with the study’s public and patient research partners, and with reference to established medical terminology directories developed by the National Institute for Health Research, the Royal College of Obstetricians and Gynaecologists, the State Government of Victoria, and Wiley.\(^7\)\(^8\)\(^9\)\(^10\) These outcomes and lay definitions were entered into the modified Delphi method, which was delivered through sequential online surveys using Delphi survey software (Delphi Manager, University of Liverpool, Liverpool, UK).

Healthcare professionals, researchers, and women with endometriosis were invited to participate. Recruitment was supported by the British Society of Gynaecological Endoscopy, the Cochrane Gynaecology and Fertility group, the Endometriosis Clinical Study Group, the World Endometriosis Society, and an active social media campaign. The Delphi method does not depend on statistical power, and therefore group error should reduce as the number of participants increases.\(^11\) Between ten and 15
participants have been demonstrated to yield sufficient results and ensure validity.\textsuperscript{11–13} We aimed to recruit at least 18 participants for each stakeholder group, anticipating an overall attrition rate of 20\% between Delphi survey rounds.

In round 1, participants scored individual outcomes on a nine-point Likert scale, anchored between one (labelled ‘not important’) and nine (labelled ‘critical’).\textsuperscript{14} This scale was devised by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) working group to facilitate the ranking of outcomes according to their importance, and has been adopted widely by core outcome set developers. Participants were able to select an ‘unable to score’ category if they did not have enough expertise or experience to score an individual outcome. At the end of the survey, participants were able to suggest additional outcomes. After the round-1 survey had closed, the scores for each outcome were aggregated across individual stakeholder groups. The percentage of participants scoring each outcome at every possible response from one to nine was calculated and tabulated for individual stakeholder groups (healthcare professionals, researchers, and women with endometriosis). Additional outcomes were considered by the steering group and outcomes that had not been present in round 1 were entered into round 2.

In round 2, participants received their own scores and individual stakeholder group feedback for each round-1 outcome. Participants were asked to reflect on their own scores and on the scores of other participants before rescoring each outcome. Before completing the survey, participants were able to score additional outcomes suggested by participants in the round-1 Delphi survey. The 70/15\% consensus definition advocated by the COMET initiative was applied to the round-2 Delphi survey results.\textsuperscript{6} A consensus outcome was identified when over 70\% of participants in each stakeholder group scored the outcome as ‘critical for decision making’ (with a score of 7–9) and less than 15\% of participants in each stakeholder group scored the outcome as being ‘of limited importance for decision making’ (with a score of 1–3).

Following the Delphi survey, a face-to-face consensus development meeting was arranged to discuss the survey results. The consensus development meeting used a modified nominal group technique to further prioritise consensus outcomes. Healthcare professionals, researchers, and women with endometriosis were invited to participate. The modified nominal group technique does not depend on statistical power. We aimed to recruit between ten and 15 participants, as this number has yielded sufficient results and assured validity in other settings.\textsuperscript{11,15}

The modified nominal group technique was delivered through a half-day consensus development meeting. At the start of the meeting, the results of the Delphi survey were reviewed, and all consensus outcomes were entered into the process. Participants added two further outcomes that had not been scored in the Delphi survey: termination of pregnancy and improvement in the most troublesome symptom. Each participant was asked to contribute their opinions on the suitability of individual outcomes forming a component of the final core outcome set. Participants were encouraged to reformulate outcomes to improve clarity or comprehension and, where appropriate, group outcomes in an outcome domain. For example, damage to bowel, damage to the nervous system, and damage to renal tract were grouped into the outcome domain labelled adverse events. This would enable a degree of flexibility to tailor adverse event reporting in future endometriosis trials to the experimental intervention being evaluated. Following the initial discussion, outcomes were divided into three initial categories: (i) outcomes to be considered for inclusion in the final core outcome set; (ii) outcomes where no consensus existed; and (iii) outcomes that should not be considered for inclusion in the final core outcome set. Participants were invited to discuss the ordering of the outcomes within each category. The discussion focused upon ranking the outcomes being considered for inclusion in the final core outcome set and the outcomes where no consensus existed. During the discussion, the outcomes could be moved between the categories. Following the discussion, the final core outcome set for endometriosis was agreed.

This study was funded by the Catalyst Fund, the Royal Society of New Zealand, and Endometriosis Millennium Fund, Royal College of Obstetricians and Gynaecologists. The funders had no role in the design and conduct of the study, the collection, management, analysis, or interpretation of the data, or in the preparation of the article.

**Results**

When considering the Delphi survey, round 1 was completed by 354 participants representing 29 countries (Table 1). Round 2 was completed by 238 of the original participants (67\%).

Fifty-five outcomes were entered into the round-1 Delphi survey (Figure 1). In response to the outcomes suggested by participants, the steering group included 34 new outcomes to round 2 (Appendix S1). Therefore, 89 outcomes were entered into round 2. Following round 2, 18 outcomes reached consensus and were entered into the consensus development conference.

Twenty-four participants, representing seven countries, participated in the consensus development meeting. Eighteen consensus outcomes were entered into the modified nominal group technique. Participants entered an additional ten no-consensus outcomes into the process, including physical functioning, spontaneous conception following medical or surgical treatment of endometriosis, and...
cumulative live birth rate. Therefore, 28 potential core outcomes were discussed in total. Participants prioritised 13 outcomes for inclusion in the core outcome set for future endometriosis research (Figure 1).

Discussion

Main findings

Using robust consensus science methods, healthcare professionals, researchers, and women with endometriosis have developed a core outcome set to standardise outcome selection, collection, and reporting across future randomised controlled trials and systematic reviews evaluating potential treatments for endometriosis. The core outcome set is applicable to potential treatments for pain, infertility, and other symptoms associated with endometriosis.

Strengths and limitations

Our core outcome set development study met the methodological standards for core outcome set development recently published by the COMET initiative. All 11 standards were achieved across three broad domains, including scope specification, stakeholder involvement, and consensus development process. When considering the Delphi survey, 354 participants from 25 countries engaged with the prioritisation of outcomes. The study included women with endometriosis as both steering group members and as participants. As steering group members, they provided valuable oversight, design, and development of the Delphi survey. As participants, they shared their views during the Delphi survey and contributed to the prioritisation of outcomes for inclusion within the final core outcome set during the consensus development meeting.

This consensus study is not without limitations. Consideration should be given to the representativeness of the study participants. For example, when considering the Delphi survey, there was a higher response from participants who lived in Europe (225 participants, 63%). We appreciate that limitations in the representativeness of the sample could have affected the outcomes prioritised. The best approaches to combining the views of different stakeholders have been investigated rarely in previous core outcome set development studies. Several studies have included a heterogeneous group of participants, representing multiple stakeholder groups, included in a single panel. When these data were combined, with no consideration of the separate stakeholder groups, the resulting outcome set depended upon the relative proportions of the individual stakeholder groups participating. Further methodological research is required to explore panel size, panel composition, and consensus definition.

The attrition rate for the Delphi survey was 33%, which is comparable with other core outcome development studies. It may be possible to reduce attrition by reducing the number of participants, removing outcomes that reached consensus in subsequent survey rounds, or reducing the number of survey rounds. Attrition must be balanced against the requirement to encourage a diverse range of stakeholders to participate, the need to include a comprehensive long list of potential core outcomes into the Delphi survey, and the need for participants to be able to reflect on and re-score individual outcomes in relation to each other.

The a priori consensus definition used in this study could be perceived as another potential limitation. The modified Delphi method used the 70/15% consensus definition, which is subjective and not based upon research.

Table 1. Participant characteristics

<table>
<thead>
<tr>
<th></th>
<th>Modified Delphi method</th>
<th>Modified nominal group technique</th>
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<tbody>
<tr>
<td></td>
<td>Round 1: n = 354</td>
<td>Round 2: n = 238</td>
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<tr>
<td>Stakeholder group, n</td>
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<tr>
<td>Health professionals</td>
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<td>Gynaecologist with an</td>
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<td>interest in infertility</td>
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<td>Gynaecologist with an</td>
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<tr>
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<td>Gynaecologist with an</td>
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<td>48</td>
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<td>interest in pain and</td>
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<tr>
<td>infertility</td>
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<tr>
<td>Other</td>
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<td>14</td>
</tr>
<tr>
<td>Researchers</td>
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<td>28</td>
</tr>
<tr>
<td>Women with endometriosis</td>
<td>206</td>
<td>119</td>
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<td>Gender, n</td>
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<td>40–49</td>
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<tr>
<td>Prefer not to say</td>
<td>2</td>
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evidence or statistical evaluation. Further methodological research is required to develop an appropriate consensus definition. It is likely that this definition would need to be dynamic with specific conditions or combination criteria, which could consider the unique scoring distribution of the Delphi survey participants.

**Interpretation**

A recent research prioritisation exercise has highlighted the most pressing research questions as perceived by healthcare professionals and women with endometriosis. Many of these research questions will require the evaluation of potential treatments for endometriosis within a randomised controlled trial setting. Complex issues, including a failure to take into account the perspectives of women with endometriosis when designing trials, variations in outcome measures, and outcome reporting bias, could undermine the translation of future endometriosis research into clinical practice. The core outcome set for endometriosis should standardise outcome collection and reporting across future endometriosis trials and will help to ensure that future research ultimately improves the care that women with endometriosis receive.

Live birth is considered the most appropriate primary outcome for trials evaluating potential treatments for infertility. Following up trial participants for over 9 months could have implications for the resources that individual trials require. The development of a core outcome set for endometriosis should provide additional leverage for researchers to request sufficient funding to enable the collection of core outcomes, including live birth. The core outcome set presents an opportunity to standardise the collection of outcomes: for example, pregnancy can be confirmed by urinary beta human chorionic gonadotropin (HCG), serum beta HCG, and ultrasound. When presented with different outcomes prioritised by the Delphi survey participants, researchers can use the core outcome set to request relevant data from trial participants.

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**Figure 1. Flow of participants and outcomes.**

<table>
<thead>
<tr>
<th>Systematic review</th>
<th>55 potential core outcomes</th>
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</thead>
<tbody>
<tr>
<td>Delphi survey round 1</td>
<td>55 potential core outcomes</td>
</tr>
<tr>
<td>116 healthcare professionals</td>
<td>32 researchers</td>
</tr>
<tr>
<td>206 women with endometriosis</td>
<td>34 additional outcomes entered</td>
</tr>
<tr>
<td>Delphi survey round 2</td>
<td>89 potential core outcomes scored</td>
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<tr>
<td>91 healthcare professionals</td>
<td>28 researchers</td>
</tr>
<tr>
<td>119 women with endometriosis</td>
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<tr>
<td>Consensus meeting</td>
<td>18 consensus outcomes entered</td>
</tr>
<tr>
<td>8 healthcare professionals</td>
<td>6 researchers</td>
</tr>
<tr>
<td>10 patients</td>
<td>10 outcomes entered by participants</td>
</tr>
</tbody>
</table>

**Core outcome set for endometriosis**

- Overall pain
- Improvement in the most troublesome symptom
- Quality of life
- Viable intrauterine pregnancy confirmed by ultrasound
- Pregnancy loss, including ectopic pregnancy, miscarriage, stillbirth, and termination of pregnancy
- Live birth
- Time to pregnancy leading to live birth
- Gestational age at delivery
- Birthweight
- Neonatal mortality
- Major congenital abnormalities
- Adverse events
- Patient satisfaction with treatment

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the modified nominal group technique enabled participants to rank different outcomes and to make a recommenda-
tion: in this case, viable intrauterine pregnancy confirmed by ultrasound. Several core outcomes, including gestational age at delivery, birthweight, and neonatal mortality, were included to provide important safety signals for future ran-
domised trials.

It is considered good practice for researchers developing clinical trial protocols to use the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) state-
ment.19 This statement outlines the scientific, ethical, and
administrative elements that should be addressed and specifically recommends the use of core outcome sets, where they exist.

The Core Outcomes in Women’s and Newborn Health (CROWN) initiative aims to tackle poor outcome selection, collection, and reporting within our speciality.17 Participat-
ing journals will initially strongly encourage, and over the longer term require, researchers to report the core outcome set for endometriosis within randomised trial reports and offer conclusions based on these outcomes. Where core outcomes have not been collected, the researchers will be asked to report this deficiency and its implications for their findings.20

Objectively demonstrating the uptake of the core out-
come set for endometriosis will be important in quantifying its contribution in tackling research waste by reducing the use of poorly selected, collected, and reported out-
comes. Assessing the uptake of the core outcome set for endometriosis will be undertaken by examining registry records, published protocols, randomised controlled trials, and systematic reviews, and undertaking a citation analysis. In addition, further research is planned to examine and understand the reasons why researchers do, and do not, implement the core outcome set for endometriosis.

This study is complimentary to other initiatives that the endometriosis research community has previously engaged with in standardising important aspects of research design. The Art and Science of Endometriosis meeting, convened by the National Institutes of Health, has published recommen-
dations regarding the standardisation of research design in several areas, including entry criteria and outcome measures for pain symptoms. The World Endometriosis Research Foundation Endometriosis Phenome and Biobanking Harmonisation Project has published tools for the standardi-
sation of research design in several areas, including clinical, covariate, and surgical phenotype recording, and specimen collection, processing, and storage.

The work will continue, involving global participants from a range of stakeholder groups, including healthcare professionals, researchers, industry representatives, and patient representatives, reflecting the enthusiasm of our specialty to work together to improve research design, clinical research conduct, and clinical care.

Conclusion

This study has developed a core outcome set that should be implemented across future randomised trials and sys-
tematic reviews evaluating potential treatments for endometriosis to standardise outcome selection, collection, and reporting. Future research is required to associate core outcomes with high-quality definitions and measurement instruments. The core outcome set for endometriosis will be reviewed every 3 years or in response to a paradigm shift in diagnosis, treatment, or understanding.

Disclosure of interests

MLH has received travel grants from Merck-Serono and Geurbet, research funding from AbbVie, Merck, Origio, and Myovant, and has been a consultant to Vifor Pharma. AWH has received consultancy fees from AbbVie, Ferring, Nordic Pharma, and Roche Diagnostics. NPJ has received conference expenses from Bayer Pharma, Merck-Serono, and Merck and Co., research funding from AbbVie, and has been a consultant to Guerbet, Myovant Sciences, and Vifor Pharma. LR has received research funding from Ferr-
ing Australia, Merck-Serono, and MSD, and chairs the Ferring Australia advisory board. The remaining authors report no competing interests. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship

Study concept and design: JMD, MH, MV, CB, SL, NPJ, BM, and CMF. Acquisition of data: JMD, MH, MV, SL, NPJ, BM, and CMF. Analysis and interpretation of data: JMD, MH, MV, JB, CB, BC, RD, JLE, MH, AWH, LH, SK, SL, NPJ, VM, BM, AO, LP, MBR, LR, AV, RW, and CMF. Drafting of the manuscript: JMD, MH, and CMF. Critical revision of the manuscript for important intellectual con-

Details of ethics approval

Ethics approval was not required as the study was not a clinical trial, did not assess a device or expose a patient to ionising radiation, did not require the collection or storage of any material, specimens, or protected information, recruit patients/carers through the UK National Health Ser-
vise, involve anyone with lack of capacity, or prisoners, or xenotransplantation, and was not a social care project funded through the Department of Health.
Funding
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Acknowledgements
We would like to thank the healthcare professionals, researchers, and patient representatives who participated in the Delphi survey and consensus development meetings.

Supporting Information
Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Delphi survey results, reported as the percentage of participants scoring the outcome as being critical.

References

Appendix 1
endo:outcomes – an International Collaboration Harmonising Outcomes and Outcome Measures for Endometriosis Research
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