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RESEARCH ARTICLE

General obstetrics

Development of core outcome sets for studies relating to awareness and clinical management of reduced fetal movement

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Abstract

Objective: This study aimed to create core outcome sets (COSs) for use in research studies relating to the awareness and clinical management of reduced fetal movement (RFM).

Design: Delphi survey and consensus process.

Setting: International.

Population: A total of 128 participants (40 parents, 19 researchers and 65 clinicians) from 16 countries.

Methods: A systematic literature review was conducted to identify outcomes in studies of interventions relating to the awareness and the clinical management of RFM. Using these outcomes as a preliminary list, stakeholders rated the importance of these outcomes for inclusion in COSs for studies of: (i) awareness of RFM; and (ii) clinical management of RFM.

Main outcome measures: Preliminary lists of outcomes were discussed at consensus meetings where two COSs (one for studies of RFM awareness and one for *studies of clinical management of RFM*).

Results: The first round of the Delphi survey was completed by 128 participants, 66% of whom ($n = 84$) completed all three rounds. Fifty outcomes identified by the systematic review, after multiple definitions were combined, were voted on in round one. Two outcomes were added in round one, and as such 52 outcomes were voted on in two lists in rounds two and three. The COSs for studies of RFM awareness and clinical management are comprised of eight outcomes (four maternal and four neonatal) and 10 outcomes (two maternal and eight neonatal), respectively.

Conclusions: These COSs provide researchers with the minimum set of outcomes to be measured and reported in studies relating to the awareness and the clinical management of RFM.

KEYWORDS
core outcome set, Delphi survey, fetal movement, systematic review

1 | INTRODUCTION

1.1 | Reduced fetal movement

Reduced fetal movements (RFM) are defined as a subjective decrease or change in a baby's typical pattern of movements in utero.[1] The current guidance in a number of countries is for anyone who is pregnant to contact a midwife or maternity unit if they perceive their baby to be moving less than usual or not at all.[2–4] Maternal concern regarding RFM leads to a presentation to maternity services in 5%–15% of pregnancies.[5] Around 70% of these pregnancies have a normal outcome,[6–8] although observational studies have recurrently demonstrated that RFM is associated with adverse pregnancy

outcomes, including fetal growth restriction and stillbirth, supporting the potential for a common aetiology.[9,10]

1.2 | Studies of interventions for reduced fetal movement

Studies aiming to evaluate interventions for RFM have employed two main types of interventions: (i) interventions aiming to encourage maternal and/or clinical awareness of RFM, such as encouraging an awareness of the pattern, strength and frequency of fetal movements or kick counting;[11,12] and/or (ii) interventions evaluating clinical management interventions, e.g. interventions comprising further monitoring and/or clinical testing, such as cardiotocography or ultrasound, to identify whether RFM is an indicator of an underlying condition that may warrant further clinical intervention or even expedited birth.[13,14]

A recent systematic review and meta-analysis showed that encouraging an awareness of fetal movement may be associated with a reduction in neonatal intensive care unit (NICU) admissions, low Apgar scores and reduced maternal anxiety, although the certainty of evidence and variation in outcome reporting impeded the analyses.[15] This review identified the need for core outcome sets (COSs) for studies relating to the awareness and the clinical management of RFM, to ensure that future studies all measure and report on outcomes that stakeholders consider most important, and to improve the consistency of outcome reporting for future syntheses of evidence.

A COS describes a standardised set of outcomes that should be measured and reported in all studies in a specific area, as a minimum.[16] This study aimed to develop COSs for the measurement and reporting of interventions relating to the awareness and the clinical management of RFM, although these COSs may also be applicable to other study designs.

2 | METHODS

2.1 | Study design

This project was registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative (http://comet-initiative.org/Studies/Details/928), 24 September 2020. In brief, the study consisted of three parts: (i) a systematic review to identify relevant outcomes, which were then entered into an online survey; (ii) an online three-round Delphi survey; and (iii) three consensus meetings. The methods are described in full in the study protocol,[17] which was developed in accordance with the COMET handbook.[16]

2.2 | Participants

Eligible participants were: (i) researchers, research funders and policymakers actively involved in work related to RFM; (ii) clinicians (midwives, obstetricians, neonatologists and GPs/family physicians) with experience of caring for women with RFM; and (iii) parents (anyone who is or who has been pregnant and their partners, if applicable). We recruited participants through professional organisations, electronic discussion lists and patient organisations or charities. Authors of all studies included by the systematic review were invited to participate; we also encouraged snowball sampling, whereby we requested that participants forward the survey to others that they considered eligible to participate.

Participants of the Delphi survey received all information regarding the study as part of the invitation email or included with the link to the survey on social media. The personal data for all participants were solely accessible to members of the research team and all survey responses were confidential. Participants had the right to withdraw at any point. Ethical approval was obtained from the University of Manchester Research Ethics Committee (ref. 2021-11160-18073) and consent was obtained from all participants before they completed the survey.

2.3 | Stage one: Systematic review

A systematic literature review was conducted to identify outcomes measured in studies of interventions designed to encourage an awareness of RFM and/or evaluate the subsequent clinical management of RFM in non-anomalous singleton pregnancies after 28 weeks of gestation. We included randomised controlled trials and non-randomised studies with clearly reported mechanisms of group formation, clearly defined inclusion criteria, and clearly described methods of ascertaining eligible patients and their recruitment. Studies were included regardless of publication status, date and language.

The following databases were searched from inception to 31 March 2021: Medline, Medline In-Process & Other Non-Indexed Citations, Embase, EBSCO CINAHL Plus, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Pregnancy and Childbirth Group's Trials Register and the Cochrane Database of Systematic Reviews. Other trial registries such as clinicaltrials.gov, WHO International Clinical Trials Registry Platform (ICTRP) (https://www.who.int/clinical-trials-registry-platform) and the EU clinical trials register were searched, as well as databases such as OpenGrey (www.opengrey.eu), JBI EBP database (https://jbi.global/) and the National Institute for Health and Clinical Excellence website (NICE; www.nice.org.uk) to find unpublished studies. The reference lists of the included articles were reviewed for additional studies.

A list of outcomes reported by each study was extracted, as well as how they were defined and measured (e.g. if a standardised scale was used), and outcomes were grouped as maternal or neonatal, and then into domains within these categories. This final list of outcomes was used in stage two of the COS development process.

2.4 | Stage two: Delphi survey

A sequential three-round electronic international Delphi study with key stakeholders was conducted using REDCap 10.1.2 to produce a preliminary COS.[18] The Delphi survey and following consensus meeting allowed the possibility of producing either one COS (for all studies relating to encouraging an awareness and/or evaluating the clinical management of RFM) or two COSs (one for studies encouraging an awareness of RFM and another for studies evaluating the clinical management of RFM). This followed the precedent set by other COSs in maternity care that have started by running two surveys simultaneously to determine whether one or two COSs should be produced.[19,20]

Round one collected demographic data, including nationality, age, stakeholder group and role. Participants were presented with all outcomes identified from the systematic literature review and asked to rate the importance of each using a nine-point Likert scale, where a score of 1–3 indicates limited importance, a score of 4–6 indicates importance and a score of 7–9 indicates critical importance. Participants were prompted to add additional outcomes that they felt were important but were not included in the preliminary list.

In round two, all participants who completed the first round were asked to rescore all outcomes using the same nine-point Likert scale, including additional suggested outcomes from round one. From round two onwards, participants were asked to rate the importance of each outcome to studies of: (i) awareness of RFM; and (ii) clinical management of RFM. Outcomes were presented in two corresponding lists, and ratings for the two lists were reviewed and analysed separately. In rounds two and three, participants were also provided with feedback showing them their own previous scores, and the distribution of scores for each outcome by stakeholder group.

Standardised consensus criteria were applied to the results through rounds two and three to reach the preliminary list of outcomes to be included (Table 1). Outcomes were included in round three if they were rated as 'consensus in' or 'no consensus'; outcomes rated as 'consensus out' were removed. Outcomes were removed from lists (i) and (ii) of the survey individually, based on their ratings in each list.

All participants who completed round two were invited to take part in round three. In round three, participants were again provided with feedback and asked to rerate the remaining outcomes in the same way as in round two. Outcomes defined as 'consensus out' and 'no consensus' were removed at the end of round three.

2.5 | Stage three: Consensus meetings

Two initial consensus meetings were held at different times of day to facilitate international participation. These meetings were held online to maximise attendance during the continuing COVID-19 pandemic. These meetings included a presentation of the Delphi survey findings, including the final list of outcomes by category (i.e. awareness and clinical management) and how they were voted for by each stakeholder group. The presentation was followed by a discussion and vote on each outcome for each list. Voting at these meetings was electronic and anonymous. Outcomes were included if voted for by at least 70% of participants. A third meeting was then held to discuss and vote on any outcomes that were included at one meeting only.

3 | RESULTS

3.1 | Systematic review

The systematic literature review identified 225 outcomes from 28 studies. After duplicate outcomes from different studies (or those that were considered to be similar) were removed or combined, 50 unique outcomes (24 maternal outcomes and 26 neonatal outcomes) were forwarded to round one of the Delphi survey (Table S1).

3.2 | Delphi survey

Round one was completed by 128 participants, of whom 31% were parents ($n = 40$), 15% were researchers ($n = 19$), 51% were clinicians ($n = 65$) and 3% chose 'other' when responding ($n = 4$). Of these 128 participants, 80 were from the UK (33 from England, four from Wales, two from Scotland and one from Northern Ireland; 40 did not specify the country), 11 were from Zimbabwe, 10 were from Ireland, six were from Australia, four were from Sweden, four were from the USA, and the remaining 13 participants were from Austria, Canada, India, the Netherlands, New Zealand, Turkey and Uganda.

Two new outcomes were added after round one, having been suggested by two or more participants. These were: healthcare costs (additional costs resulting from extra visits or scans) and maternal well-being (maternal mental health throughout pregnancy, including the birth experience and whether any trauma was experienced).

TABLE 1 Consensus criteria for outcomes.

Definition	Criteria
Consensus in	Scored as 7–9 by 70% or more of all participants, including at least one from each stakeholder group, and as 1–3 by less than 15% of participants
Consensus out	Scored as 1–3 by over 70% of participants, and as 7–9 by less than 15% of participants
No consensus	Any other combination of scores

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Round two was completed by 77% (99/128) of participants who completed round one, of whom 30% were parents ($n = 30$), 19% were researchers ($n = 19$), 47% were clinicians ($n = 47$) and 3% fell under the 'other' category ($n = 3$). Of these 99 participants, 63 were from the UK (25 from England, three from Wales, three from Scotland and Northern Ireland; 32 did not specify the country), seven were from Zimbabwe, seven were from Ireland, five were from Australia, and the remaining 17 participants were from Canada, India, the Netherlands, New Zealand, Sweden, Turkey, Uganda and the USA. No outcomes met the 'consensus out' criteria after round two, and so all 52 outcomes were forwarded to round three.

Round three was completed by 85% (84/99) of the participants who completed round two (65% of the initial participants, 84/128): 31% were parents ($n = 26$), 23% were researchers ($n = 19$), 44% were clinicians ($n = 37$) and 2% were 'other' ($n = 2$). Of these 84 participants, 46 were from the UK (20 from England and three from Wales and Northern Ireland; 23 did not specify the country), seven were from Ireland, seven were from Zimbabwe, six were from Australia, four were from the USA, and the remaining 14 were from Canada, India, the Netherlands, New Zealand, Northern Ireland, Sweden, Turkey and Uganda. After round three, 23 outcomes were rated as 'no consensus' for studies aiming to encourage an awareness of RFM, and 15 outcomes were voted as 'no consensus' for studies aiming to improve the clinical management of RFM. No outcomes were rated as 'consensus out'. This left 29 and 37 outcomes, respectively, to be voted on at the consensus meetings. Consensus for all outcomes after round three are shown in Table S2.

3.3 | Consensus meetings

Overall, 17 participants (three parents, five researchers, and nine clinicians) from eight different countries (Australia, England, Ireland, the Netherlands, New Zealand, Uganda, the USA, and Zimbabwe) attended one or more of the consensus meetings. All meetings were held online; the first two meetings lasted between 3 and 4 h, with the final meeting lasting just under 2 h. The final meeting allowed perspectives from both groups to be combined for outcomes that were not voted 'consensus in' at the first two meetings. The outcomes discussed at the final meeting were: (i) the acceptability of information about RFM, induction of labour, gestation at birth and NICU admission, for studies of RFM awareness; and (ii) caesarean section, birthweight, gestation at birth, hypoxic ischaemic encephalopathy, NICU admission, NICU admission after 37 weeks of gestation, preterm birth and small for gestational age, for studies of clinical management. We judged that outcomes included in the COS lists for studies aiming to encourage awareness and studies aiming to improve management were sufficiently different. As such, two COSs were created, shown in Tables 2 and 3.

TABLE 2 Core outcome set for studies relating to the awareness of reduced fetal movement (RFM).

Maternal outcomes	Neonatal outcomes
Acceptability of information about RFM	Gestation at birth
Duration of RFM before presenting to hospital	Neonatal death
Maternal knowledge of RFM	Perinatal death
Number of presentations with RFM	Stillbirth

TABLE 3 Core outcome set for studies relating to the clinical management of reduced fetal movement.

Maternal outcomes	Neonatal outcomes
Caesarean section	Birthweight
Induction of labour	Gestation at birth
	Hypoxic ischaemic encephalopathy
	Neonatal death
	Neonatal intensive care unit admission
	Perinatal death
	Preterm birth
	Stillbirth

3.4 | Additional analyses

Wilcoxon signed-rank tests were performed, using the median scores for each stakeholder group for each outcome, to determine whether there were statistically significant differences in the ways that the groups scored outcomes between rounds. This was only performed for the scores from rounds two and three because of a change in survey structure after round one. Median scores were higher for all groups in round three (Table S3).

Although median scores were significantly different between rounds, this only translates as small increases in perceived importance; scores for each stakeholder group were either the same or within one point on the Likert scale for rounds two and three (the only exceptions being neonatal depression, for management studies, scored as 6 in round three and 7.5 in round two by researchers, and the dysmaturity score, for awareness studies, scored as 7 in round three and 5.5 in round two by researchers). Median scores for all outcomes in rounds two and three are shown in Tables S4 and S5.

4 | DISCUSSION

4.1 | Principal findings

We have developed separate COSs for studies relating to the awareness of RFM and for studies relating to the clinical management of RFM using robust methods and following a predefined protocol, including an international sample of participants from multiple stakeholder groups. The final COS for studies of awareness includes eight outcomes (four

maternal and four neonatal). For studies of the clinical management of RFM the COS includes 10 outcomes (two maternal and eight neonatal). Studies planning on employing combined interventions, i.e. with components aimed at encouraging an awareness of RFM as well as its subsequent management, should measure outcomes specified by both lists. Additional outcomes may also be measured if relevant.

4.2 | Results

These COSs include eight and ten outcomes, or 14 outcomes if the COSs are combined. This is similar to other COSs used for women's and newborn health,[21] including recent COSs for studies of fetal growth restriction and pre-eclampsia.[20,22] A systematic review of studies of interventions for RFM showed that not all of the outcomes selected for these COSs are measured routinely.[15] This Delphi process has shown that outcomes such as the acceptability of information about RFM and maternal knowledge of RFM are important to parents, clinicians and researchers from a range of backgrounds, and yet there are no established methods for measuring these outcomes. Only one published study to date has measured the acceptability of the information given to participants about RFM,[23] and, to our knowledge, none have quantified maternal knowledge of RFM in relation to an intervention.

4.3 | Research implications

These COSs have been developed to determine the outcomes that should be measured by future studies of RFM. Further research is needed to develop consensus on how or when the outcomes in these COSs should be measured. Specifically, means to reproducibly assess the acceptability of information about RFM and maternal knowledge of RFM need to be developed for these outcomes to be measured. In addition, consideration should be given as to whether outcomes such as gestation at birth and birthweight are reported as continuous rather than categorical outcomes (as this affects how they can be used in systematic reviews and meta-analyses), whether there is overlap between some of our outcomes (such as gestation at birth and preterm birth) and how to measure outcomes that may manifest as long-term symptoms or signs, such as hypoxic ischaemic encephalopathy. Trials such as TRUFFLE and INFANT have managed this by first publishing the short-term outcomes and then measuring long-term outcomes after a 2-year follow-up period.[24,25] A list of definitions used by the studies in our systematic review, for all outcomes included in our COSs, can be seen in Table S6. This may be useful in future for researchers aiming to determine how to measure these outcomes. The authors recognise that some items overlap, e.g. stillbirth, neonatal death and perinatal death; this is in part because the outcomes were considered separately in the consensus meeting. For example, this means that perinatal death (which is calculated from stillbirths and early neonatal deaths in the UK) is included as an outcome, as well as its constituent parts. The authors also recognise that the definitions employed will reflect the context of the research, as the gestational age at which stillbirth is defined varies worldwide.

4.4 | Strengths and limitations

This COS process followed COMET guidance and a well-established method for reaching consensus. Participants represented each of our desired three stakeholder groups throughout the Delphi survey and at the consensus meeting, which ensured that the views of parents were heard alongside researchers and clinicians. Voting at the consensus meeting was anonymous and electronic. Participants were from 16 countries, including both high- and low-resource settings, which is higher than the median number of countries involved in the development of COSs.[26] The attrition rate from round one to round three was 34%, in line with the range of 21%–48% found by a review of COSs in women's and newborn health.[21]

A large proportion of respondents (44%) were clinicians, although this was split between midwives and obstetricians. Parents represented almost a third (31%) of our sample at the end of round three. Ideally, there would have been more balance between the groups, although many of the clinicians who took part have also published research related to RFM and/or have worked on COS development. Clinicians were also in the majority at the consensus meetings (9/17 participants, 53%). To mitigate any influence of this bias on the final COSs, we ensured that there was parent representation at the initial and final consensus meetings, and made sure that parents' voices were heard at these meetings by adopting an independent chairperson who did not vote on outcomes.

Although we achieved targets for recruitment and the consensus meeting, the survey was only provided in English, which has the potential to restrict the number of responses;[27] however, we were limited by the time and resources available. This is perhaps reflected in the larger number of responses from the UK and other English-speaking countries. We did not have demographic information regarding individuals who ceased to participate to determine whether they differed from those who continued to participate, although the proportion of participants from different groups did not change between different rounds of the Delphi exercise. Ideally, we would have been able to reach more participants from a greater number and range of countries, especially lower resource settings. Holding multiple consensus meetings online facilitated international attendance but also created the need to consolidate the results from both meetings; discussions may have been different in a single meeting including all participants.

5 | CONCLUSION

Following on from research into the management of RFM identified by the Stillbirth Priority Setting Partnership,

which prioritised the question, 'Which investigations identify a fetus at risk of stillbirth after a mother believes she has experienced reduced fetal movements?',[28] COSs have now been made available for use in studies relating to awareness and the clinical management of RFM. These COSs provide researchers with a minimum set of outcomes that should be recorded, facilitating comparisons of interventions. We have taken steps to ensure that the views of parents are adequately represented in this study and the final COSs.

AUTHOR CONTRIBUTIONS

All authors contributed to the study design. DJLH was responsible for data curation and formal analysis. The first draft of the article was written by DJLH; further drafts were reviewed, edited and approved by all authors.

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CONFLICT OF INTEREST STATEMENT

None declared.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable for this article as no new data were created or analysed in this study.

ETHICS APPROVAL

Ethical approval was obtained from the University of Manchester Research Ethics Committee (ref. 2021-11160-18073).

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SUPPORTING INFORMATION

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

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