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ORIGINAL RESEARCH

A core outcome set and reporting checklist for research on critically ill obstetric patients: An international consensus study

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Abstract

Introduction: Our objective was to develop a Core Outcome Set for Research on Critically Ill Obstetric Patients (COSCO) through international consensus, with the aim of improving consistency, comparability, and clinical relevance across studies involving this population.

Material and Methods: This international, multi-method study was conducted between February 16, 2023, and January 18, 2024. The process included a two-round online Delphi survey, three small group discussions, and a final consensus meeting. Participants comprised health service users (HSUs) with lived experience of critical illness during pregnancy and healthcare professionals from diverse specialties and geographic regions.

Results: Sixty-eight participants (11 HSUs and 57 healthcare professionals) from 16 countries scored 23 candidate items identified through a systematic review and qualitative interviews. Through consensus, 10 core outcomes and 7 reporting checklist items were selected for inclusion in all research on critical illness in obstetrics. Core outcomes included maternal all-cause mortality; cardiac arrest and the need for cardiopulmonary resuscitation (not resulting in death); severe (maternal) organ dysfunction; length of stay in the intensive care unit (ICU) and total hospital stay; readmission to hospital or ICU or repeated hospital/emergency department visits following discharge from ICU; presence of a new medical condition at the time of discharge from hospital, which was not present at the time of admission to the hospital; permanent infertility as a consequence of critical illness or intervention; perinatal loss; severe neonatal morbidity requiring prolonged neonatal ICU admission; and gestational age/preterm birth. Four additional noncore outcomes were identified

Abbreviations: COMET, Core Outcome Measures in Effectiveness Trials; COS, Core Outcome Set; COSCO, Core Outcome Set for Research on Critically ill Obstetric Patients; HCP, healthcare professionals; HSU, health service user; ICU, intensive care unit; LMIC, low and middle-income countries; NICU, neonatal intensive care unit.

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as important but may be challenging to measure consistently; these should be reported when relevant and feasible.

Conclusions: COSCO provides a standardized, consensus-based framework for outcome reporting in research on critically ill obstetric patients. Its adoption will strengthen methodological rigor, reduce reporting heterogeneity, enhance comparability across studies, and support evidence-based, patient-centered guideline development.

KEYWORDS
consensus methodology, Core outcome set, critically ill obstetric patients, Delphi method, maternal outcomes, neonatal outcomes, patient-centered outcomes

1 | INTRODUCTION

The incidence of intensive care unit (ICU) admissions during pregnancy or the postpartum period varies widely across healthcare settings, with reported rates ranging from 0.7% to 13.5%.[1] In high-income countries, ICU admission rates among pregnant individuals typically remain below 2%, whereas in low- and middle-income countries (LMIC), rates often exceed 10%.[2–4] These differences reflect not only variation in disease burden but also substantial heterogeneity in ICU definitions, available resources, and admission thresholds. As a result, ICU admission is an inconsistent marker of illness severity across and even within countries.[5] This variability complicates interpretation of reported ICU admission rates and challenges the comparability of studies in obstetric critical care.

For this study, critical illness was conceptually defined as severe acute maternal morbidity characterized by vital organ dysfunction and a high risk of death without timely intervention. This approach aligns with international guidance that emphasizes the level of physiological need rather than the physical location of care. Advanced monitoring, organ support, and intensive interventions may occur outside formal ICUs, particularly in resource-limited settings. Acknowledging these challenges is essential to understanding both the strengths and limitations of existing evidence.

Critical illness during pregnancy is uniquely complex. Maternal physiological changes, the need to balance maternal and fetal well-being, and psychosocial factors introduce layers of clinical and ethical considerations not seen in nonpregnancy populations.[6,7] Antepartum critical illness complicates decisions regarding timing, safety, and feasibility of interventions.[8] Postpartum illness may disrupt maternal–infant bonding, impede recovery, and affect family dynamics.[9] Despite these complexities, the current evidence base consists largely of observational studies, case series, and reports that display heterogeneity in outcome selection, definitions, and timing.

A systematic review of 136 studies involving ICU or high-dependency unit admissions during or after pregnancy confirmed substantial heterogeneity in outcome reporting, with inconsistent definitions, variable timelines, and limited attention to outcomes prioritized by patients themselves.[10] Qualitative interviews with individuals who had experienced obstetric critical illness emphasized the importance of patient-centered outcomes, including functional recovery, mental health, and life impact, domains rarely captured in existing research.[11]

Key message

An international consensus process identified 10 core outcomes, 7 reporting items, and 4 noncore outcomes to standardize and strengthen research on critically ill obstetric patients, improving comparability and clinical relevance across diverse settings.

Core outcome sets (COSs) have emerged as a structured approach to reducing reporting bias, harmonizing outcome selection, and ensuring that outcomes reflect the priorities of patients, clinicians, and researchers.[12,13] COSs are standardized collections of outcomes that should be measured and reported in all clinical studies for a given condition. While COSs have been developed for several obstetric conditions, no standardized framework previously existed for critically ill obstetric patients, a population with unique physiological vulnerabilities and complex care needs.

The Core Outcome Set for Research on Critically ill Obstetric Patients (COSCO) study aimed to establish a consensus-based standardized framework to guide outcome selection and reporting across studies involving obstetric critical illness. By harmonizing definitions and prioritizing patient-centered measures, COSCO is intended to strengthen methodological consistency, support meta-analysis, and promote the development of evidence-based, patient-centered clinical guidelines.

2 | MATERIAL AND METHODS

2.1 | Study overview

The COSCO study protocol was registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative (Study #916) and previously published.[14,15] This study adhered to the COMET

Handbook and the Core Outcome Set-STAndards for Development (COS-STAD) and Reporting (COS-STAR) guidelines.[13,16,17] It was conducted under the Outcome Reporting in Obstetric Studies (OROS) initiative[18] and led by an international, multidisciplinary team with experience in obstetric core outcome set development.

2.2 | Identification of relevant outcomes

Outcomes identification was informed by two previously published studies: a systematic review and a qualitative study.

The systematic review aimed to identify outcomes reported in studies involving obstetric patients with critical illness.[10] The protocol was registered with PROSPERO (CRD42017071944) and followed PRISMA guidelines. Searches of MEDLINE/PubMed, EMBASE, CINAHL, Cochrane Library, and the Joanna Briggs Institute Database of Systematic Reviews identified eligible studies published up to November 2017, restricted to English-language publications. Studies of pregnant or postpartum individuals with critical illness, using randomized and non-randomized designs, were included.[10]

The qualitative study sought to identify outcomes prioritized by individuals with lived experience of critical illness in pregnancy or the postpartum period.[11] Participants were recruited from ICU admissions at hospitals in Toronto, Canada, and Barranquilla, Colombia. Semi-structured interviews were conducted in English or Spanish between February and June 2018. Transcripts were analyzed using inductive thematic analysis.[11]

In both studies, ICU or high-dependency unit admission was used as a practical proxy for critical illness, recognizing that it reflects the need for advanced monitoring or organ support. Outcomes identified from both sources were grouped into five domains including mortality, morbidity (clinical/physiological outcomes), life impact (functioning), resource use, and adverse events, using a standardized taxonomy.[19] Items were refined and harmonized for inclusion in the Delphi process.

2.3 | Delphi survey

Participants were recruited globally between February 16 and March 30, 2023, through social media, professional society networks (e.g., Preeclampsia Foundation and Amniotic Fluid Embolism Foundation), direct invitations to corresponding authors of studies included in the systematic review,[10] and promotion at academic meetings. Recruitment was intentionally designed to ensure diversity in geography region, clinical discipline, and healthcare setting.

Eligible participants self-identified as either: (1) Health service users (HSUs), including individuals with lived experience of critical illness in pregnancy, family members, patient advocates, or representatives of patient organizations; or (2) Healthcare professionals (HCPs), including clinicians (e.g., obstetrics, obstetric medicine, critical care, anesthesia, neonatology, nursing, midwifery), researchers, COS developers, guideline developers, policymakers, and journal editors involved in caring for critically ill pregnant individuals.

The first round of the Delphi survey was launched on February 16, 2023, using the DelphiManager software (COMET Initiative), a platform designed to support global COS development.[13] The survey included plain-language explanations to ensure accessibility for nonclinician participants. A baseline questionnaire collected demographic data, including country of residence and clinical practice setting. Participants then rated each outcome on a 9-point Likert scale: 1–3 (not essential), 4–6 (important but not critical), and 7–9 (critically important). Participants could select "unable to score" and at the end could propose additional outcomes.[13] Proposed outcomes were reviewed and outcomes deemed novel and relevant by the study team were included in the second round.

Round 1 remained open for 6 weeks, with weekly email reminders sent to nonrespondents. Results were summarized using histograms generated in Microsoft Excel and R.

The second round opened on June 13, 2023, and remained open for 6 weeks. Participants were shown the histograms from Round 1 displaying the Likert scores of all participants from the previous round. They were then invited to re-score each outcome and were given the option to provide a rationale for any score changes.

Following Round 2, the median and interquartile range were calculated for each outcome. Outcomes were then categorized in Microsoft Excel according to pre-specified numerical criteria: "consensus in" if more than 70% of participants scored the outcome 7–9, "consensus out" if more than 70% scored it 1–3, and "no consensus" for all other outcomes.

2.4 | Small group discussions and consensus meeting

Reaching consensus on only a subset of outcomes during Delphi rounds is common in COS development, particularly for complex topics involving diverse stakeholder perspectives. To address this challenge, and based on prior COS development experience where many outcomes failed to reach consensus through Delphi surveys alone,[20,21] the COSCO protocol was adapted to include small group discussions before the final consensus meeting. These discussions aimed to explore divergent scoring and better understand stakeholder perspectives.

Participants included HSUs and HCPs who had completed both Delphi rounds and indicated willingness to participate in subsequent stages. Prior to the discussions, participants received a list of outcomes that had not yet reached consensus and were asked to rank their top 15 outcomes and classify each outcome as either core or important noncore.

Virtual small group discussions were held in December 2023. Participants discussed their rationale for each outcome and voted on inclusion in the final COS. Outcomes that still lacked consensus

were carried forward to the final consensus meeting, held virtually on January 18, 2024. Invitations were extended to all small group discussion participants as well as those who expressed interest in joining a small group discussion but were unable to attend due to scheduling conflicts. Attendance was limited to those available at the scheduled time, and participation was voluntary.

The final consensus meeting began with an overview of the COSCO development process and a summary of outcomes that had already reached consensus. The remainder of the meeting focused on unresolved outcomes, with particular attention to those prioritized by HSUs to ensure patient perspectives remained central in the discussion. For each outcome, participants discussed inclusion or exclusion and cast a final vote. Outcomes receiving more than 50% affirmative votes were included in the COS. This threshold was selected to allow flexibility and reflect diverse expert perspectives, consistent with approaches used in other Delphi studies to support iterative refinement of the COS.[13,22]

3 | RESULTS

The development process for COSCO is summarized in Figure 1. Initially, 24 outcomes were identified through previously published systematic review and qualitative interviews. The systematic review included 136 studies reporting on 10 109 critically ill pregnant or postpartum individuals across 39 countries. Eighteen outcomes were extracted and categorized into five core areas: mortality/survival (reported in 94.1% of studies), clinical/physiological outcomes (81.6%), resource use (85.2%), functioning/ life impact (2.9%), and adverse events (2.9%).[10]

The qualitative study identified 26 patient-important outcomes, with a strong emphasis on functioning and life impact (reported by 100% of participants), followed by resource use (75%), clinical/physiological outcomes (58.3%), mortality (25%), and adverse events (8.3%). Six unique patient-important outcomes were identified.[11]

Following review by the COSCO study team, these 24 outcomes initially identified were refined for clarity, merged where appropriate, and subdivided when necessary. This process resulted in a final list of 23 unique outcomes, which were used to inform the first round of the Delphi survey (Table S1).

In the first round, 68 participants (11 HSUs and 57 HCPs) from 16 countries completed the survey. Participant demographics are presented in Table 1. During this round, 40 additional outcomes were suggested. Most overlapped with existing items or required only minor wording adjustments. Seven novel outcomes were identified and included in the second round, bringing the total to 30 outcomes (Table S2).

The second round was completed by 44 participants (6 HSUs and 38 HCPs), reflecting a 35.3% attrition rate. Nine outcomes met the threshold for "consensus in" (>70% of participants scoring 7–9). These were: maternal all-cause mortality; cardiac arrest and the need for cardiopulmonary resuscitation not resulting in death; severe maternal organ dysfunction; perinatal loss; readmission to hospital or ICU or repeated hospital/emergency department visits following discharge from ICU; permanent infertility as a consequence of critical illness or intervention; gestational age at birth/preterm birth; baby's long-term neurodevelopmental, cognitive, and psychological outcomes; and effective communication regarding the medical situation and long-term impacts between the patient/family and their healthcare team. Twenty-one outcomes did not reach consensus (scored 4–6), and none were classified as "consensus out" (>70% scoring 1–3). Although full consensus was not achieved through the Delphi process alone, the results provided a strong foundation for further discussion.

Three virtual small group discussions were held with two HSUs (from Canada and the United States) and 10 HCPs (from Argentina, Australia, Colombia, Ecuador, Singapore, the United Kingdom, and the United States). These sessions allowed participants from diverse backgrounds to share their perspectives and explain their rationale for including or excluding each outcome. Of the 21 items discussed, 13 items were deemed important and carried forward for further review. Three items were excluded, and five that still lacked consensus were brought to the final consensus meeting.

The final consensus meeting included nine HCPs from Argentina, Australia, Colombia, Ecuador, Hong Kong, India, Uruguay, and the United States. The five remaining items were discussed in detail. Four were retained, and one was excluded.

The COSCO study team reviewed all 26 outcomes identified through the Delphi rounds and discussions (see Figure 1). Similar items were merged (for example, "severe neonatal outcome" and "neonatal ICU admission" were combined into "severe neonatal morbidity requiring prolonged NICU admission"), and wording was refined based on participant feedback (for example, "effective communication with the healthcare team" was revised to "effective communication regarding the medical situation and long-term impacts between the patient/family and their healthcare team").

This process resulted in a final list of 21 items categorized into three groups:

- 10 core outcomes applicable to all studies on critical illness in pregnancy include maternal all-cause mortality; cardiac arrest and need for cardiopulmonary resuscitation not resulting in death; severe (maternal) organ dysfunction; ICU and total hospital length of stay; readmission to hospital or ICU or repeated hospital/emergency visits after ICU discharge; presence of a new medical condition at discharge; permanent infertility due to critical illness or intervention; perinatal loss; severe neonatal morbidity requiring prolonged NICU admission; and gestational age at birth/preterm birth. (Table 2)
- Seven reporting checklist items, which, although not necessarily outcomes, are important to report in all studies on critical illness in pregnancy (Table 3).
- Four important noncore outcomes, which are important to report in studies on critical illness in pregnancy but may not always be applicable or feasible; a justification is suggested when not reported (Table 4).

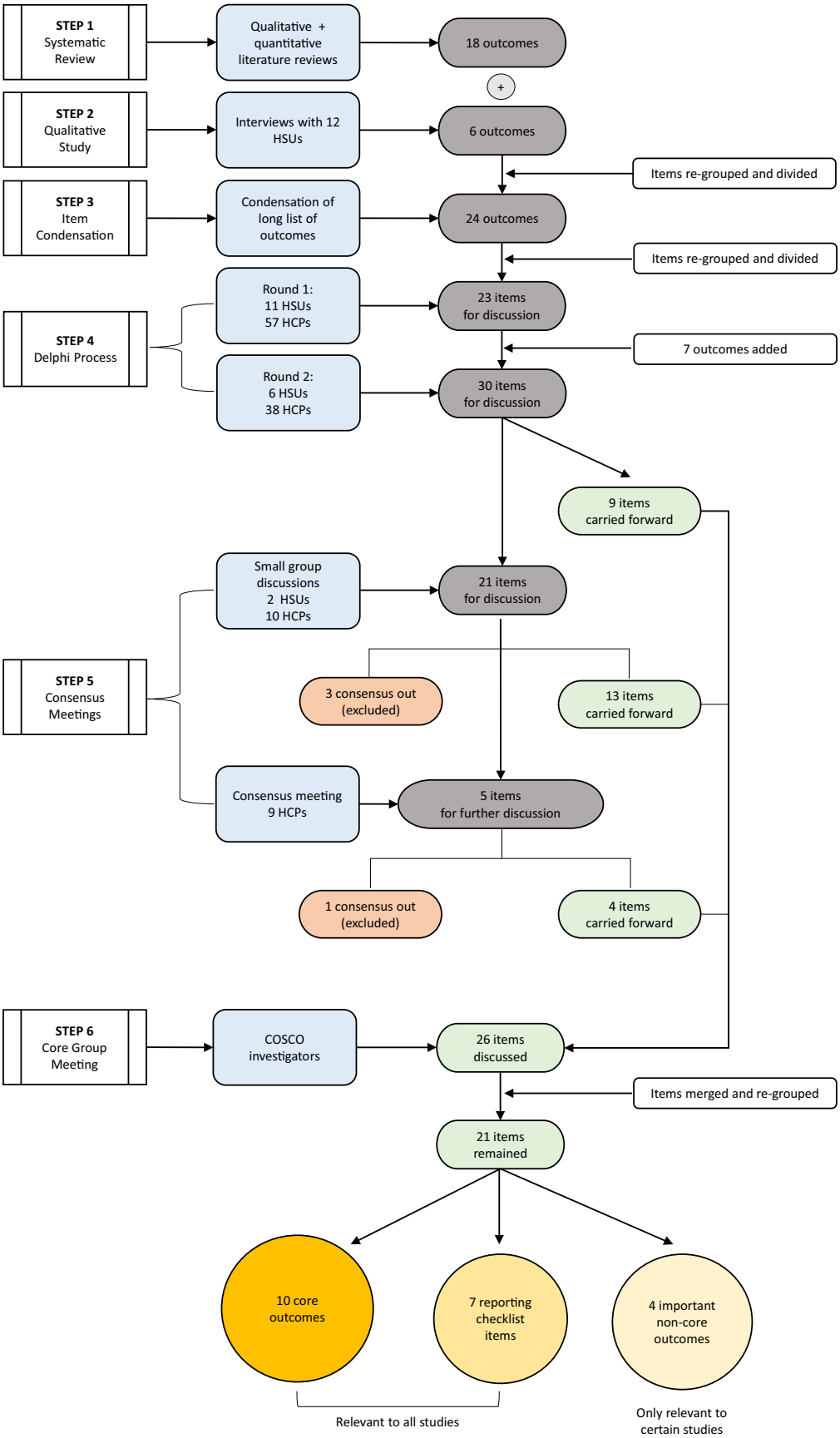

FIGURE 1 COSCO outcome decision process flowchart.

TABLE 1 Demographics of participants from the first round of the Delphi survey.

Characteristics	Participants, No. (%)
Health service users (n = 11)	
Experience with critical illness in pregnancy	
Patient	10 (91.0)
Family Member and/or Patient Advocate	1 (9.1)
Continents birthed children in	
North America	7 (63.6)
Africa	1 (9.1)
Australia and Oceania	1 (9.1)
Asia	1 (9.1)
South America	1 (9.1)
Pregnancy complications requiring critical care unit admission[a]	
Massive obstetric hemorrhage	7 (63.6)
Severe Preeclampsia or HELLP syndrome	6 (54.5)
Cardiomyopathy	2 (18.2)
Amniotic fluid embolism	1 (9.1)
Pyelonephritis	1 (9.1)
Splenic artery aneurysm rupture	1 (9.1)
Healthcare professionals (n = 57)	
Specialties[b]	
Obstetric medicine	30 (52.6)
Critical care	24 (42.1)
Obstetrics and maternal-fetal medicine	20 (35.1)
Anesthesiologists	5 (8.8)
Nursing	4 (7.1)
Other specialists (e.g., midwives, primary care, public health)	4 (7.1)
Clinical experience (in years)	
0–9	21 (36.8)
10–19	16 (28.1)
20–29	13 (22.8)
30+	7 (12.3)
Continents of clinical practice	
North America	30 (52.6)
Europe	9 (15.8)
South and Central America	8 (14.0)
Asia	6 (10.5)
Australia and Oceania	5 (8.8)
Africa	1 (1.75)
Location of practice	
Academic	39 (68.4)
Community – urban setting	28 (49.1)
Community – rural/country setting	2 (3.5)

[a]Some health service users reported more than one complication; all reported complications are listed.

[b]Some healthcare professionals reported multiple specialties; all are included in the table.

These three lists collectively represent the final output of the COSCO study and are available in fillable format in Table S3.

4 | DISCUSSION

This international initiative led to the development of COSCO, a standardized framework comprising 10 core outcomes, seven reporting checklist items, and four important noncore outcomes. The COS is intended to harmonize outcome reporting in studies on critical illness in pregnancy, reduce reporting bias, improve the quality of evidence synthesis, and support the development of robust, patient-centered guidelines.

A prior systematic review demonstrated major inconsistencies in outcome selection and definitions in research on critically ill obstetric patients. For example, only 14.5% of studies reported total length of hospital stay, 75% reported ICU length of stay, and severe maternal organ dysfunction was included in 16.9% of studies.[10] These inconsistencies limit cross-study comparability and limit meta-analyses that could more meaningfully inform clinical practice. COSCO addresses these gaps by providing a consensus-based, standardized set of outcomes that aligns patient and clinician priorities. The tiered framework developed through stakeholder discussions balances flexibility and consistency, allowing investigators to tailor outcomes to their study while still reporting a common core that supports evidence synthesis.

Adoption of COSCO is expected to enhance methodological rigor, improve comparability across studies, and guide the development of evidence-based recommendations that reflect the priorities of both HSUs and HCPs. By establishing a common lexicon and reporting framework, COSCO enables the aggregation, interpretation, and translation of research findings into clinical practice. Investigators may continue to include additional outcomes as needed, but COSCO provides a foundational structure that minimizes selective reporting bias and promotes standardized data collection.

Although COSs exist for several obstetric conditions, COSCO was designed for broad applicability across the spectrum of obstetric critical illness. Critical illness often involves multisystem conditions that extend beyond a single diagnosis. While disease-specific COSs remain valuable, COSCO offers a unifying framework for cross-cutting research. In studies where a specific condition (e.g., preeclampsia[23]) is the primary focus and includes obstetric patients who meet criteria for critical illness (e.g., ICU admission or severe organ dysfunction), researchers may consider integrating COSCO alongside the condition-specific COS to ensure comprehensive, harmonized reporting. This approach may also support future mapping efforts to reduce redundancy between outcome sets.

Effective implementation of COSCO will require complementary strategies. Advocacy could encourage funders and ethics boards to incorporate COSCO into grant evaluation and protocol review. Journals may embed COSCO within author guidelines and peer-review criteria. Practical resources, such as reporting templates, outcome-mapping guides, and training materials, may also support consistent adoption across study designs.

TABLE 2 Core outcomes for research on critical illness in obstetric patients.

Core outcome	Explanation and reporting recommendation
Maternal all-cause mortality	• For antepartum deaths, specify gestational age • For post-pregnancy deaths, specify number of days following pregnancy loss • In all cases, report the condition directly leading to death
Cardiac arrest and the need for cardiopulmonary resuscitation; not resulting in death	Specify gestational age (if antepartum) or days following pregnancy loss or childbirth
Severe (maternal) organ dysfunction	Specify affected organ(s)
Length of stay in the intensive care unit (ICU) and total stay in hospital	Report values separately, for example, ICU stay (days) + non-ICU stay (days) = Total hospital stay (days)
Readmission to hospital or ICU or repeated hospital/emergency department visits following discharge from ICU	• Report any readmissions to hospital or ICU • Specify admitting unit and list number of days admitted • Report any other unplanned hospital visits, indicated number of visits during study period
Presence at the time of discharge from hospital, of a new medical condition which was not present at the time of admission to the hospital	Specify condition(s) diagnosed
Permanent infertility as a consequence of critical illness or intervention	Specify the illness or intervention resulting in permanent infertility (e.g., hysterectomy)
Loss of baby	Yes/no If yes, clearly state the *threshold of viability* used for this study, for example, 20 weeks, 24 weeks, etc. Define perinatal loss as follows *Intrauterine/fetal loss* • Miscarriage: spontaneous fetal loss under the threshold of viability • Therapeutic abortion/pregnancy termination: medical or surgical termination of pregnancy under the threshold of viability • Stillbirth: intrauterine fetal death between the threshold of viability and birth Report gestational ages for each of the above *Neonatal death/ex utero loss* • Early neonatal death: death within the first 7 days of life • Late neonatal deaths: deaths between days 8–28 of life Report age in days following birth [Any deaths occurring after 28 days of life should be reported as infant deaths specifying the age in days where possible]
Severe neonatal morbidity requiring prolonged neonatal intensive care unit (NICU) admission	Serious or life-threatening conditions experienced by neonates. State what conditions/indicators were used to define this term. Refer to severe morbidity indicator(s) published by professional organizations and indicate which source was used If NICU admission ≥24 h, indicated length of stay in days
Gestational age at birth / preterm birth	State number of weeks

Note: These outcomes are applicable to all studies on critical illness in pregnancy.

A key strength of this study is its international scope and the inclusion of diverse HSUs and HCPs across all stages of COS development. Patient-important outcomes were prioritized from the outset, identified through qualitative interviews, Delphi surveys, and consensus discussions. This ensured that patient perspectives were not an afterthought but a central part of the process. Dedicated time was set aside during discussions to explore health service user priorities, helping ensure their perspectives remained visible throughout. By focusing on individuals with lived experience and those directly involved in their care, the study aligned with COMET guidance emphasizing engagement of those most affected.[13,24]

Although broader stakeholder groups, such as registry leaders, insurers, or regulators could offer additional insight, limiting participation to those closest to the clinical and lived experience ensured depth and relevance. This design strengthened the validity of the final outcome set. Future implementation work may benefit from expanding stakeholder engagement to support widespread adoption.

TABLE 3 Reporting checklist items for research on critical illness in obstetric patients.

Reporting checklist item	Explanation and reporting recommendation
Hospital-acquired infections	Report any infections diagnosed after ICU admission Specify the type (e.g., pneumonia, sepsis) and the timing of onset relative to admission (e.g., within 48 h, after 72 h)
Location of birth within the hospital	Specify location of birth (ICU/labor and delivery ward/operating room/other)
Mode of birth	• Mode of birth, categorizing as vaginal, assisted vaginal (forceps or vacuum), or cesarean birth • For vaginal births, indicate if the birth was spontaneous or assisted/operative. If assisted, indicate which instrument was used, for example, vacuum (type) or forceps (type) and indication for use of instrument • For Cesarean births, indicate whether it was planned or emergency. For emergency cesarean births, provide reasons such as non-reassuring fetal status, failure to progress in labor, failed induction, etc. • Include any complications related to the mode of birth
Type of analgesia/anesthesia used for labor and birth and complications	Specify type(s) of analgesia/anesthesia used (e.g., epidural, general anesthesia, spinal block, or nonpharmacological methods)
Breastfeeding concerns	Document any breastfeeding issues, specifying if the concern was related to milk production, latch, or inability to breastfeed. Include interventions or support provided (e.g., lactation consultant)
Mother–newborn separation	Length and reasons for mother–newborn separation if the critical illness involved the postpartum period (e.g., due to medical complications, NICU care) Include start and end date of separation in relation to birth.
Birthweight	State weight in grams

Note: These items, although not necessarily outcomes, are important to report in all studies on critical illness in pregnancy.

TABLE 4 Important noncore outcomes for research on critical illness in obstetric patients.

Important noncore outcomes	Explanation and reporting recommendation
Cost to families and healthcare systems from ICU admission	Given the diverse healthcare systems that include publicly-funded systems, third-party payer, and self-pay models, researchers are encouraged to estimate costs as appropriate, ideally in conjunction with health economists, as a separate study
Mother's quality of life	Various qualities of life tools are available to assess physical functioning, role limitation including maternal role, social functioning including relationship status and isolation, mental health/psychological well-being, bodily pain. Include instrument used as well as timing and frequency of measurement
Emotional impact on partner and other children at home	Various tools are available to assess this impact. Include instrument used as well as timing and frequency of measurement
Baby's long-term neurodevelopmental, cognitive, and psychological outcomes	Various tools are available depending on the age when assessed. Provide details on the instruments used and report long-term neurodevelopmental, cognitive, and psychological outcomes using standardized, age-appropriate assessment tools at specified time points (e.g., 12 months, 5 years, etc.)

Note: These items are important items to report in studies on critical illness in pregnancy but may not always be applicable or feasible. We suggest providing a justification when not reported.

Several limitations warrant consideration. The initial evidence base used to identify candidate outcomes was derived from a systematic review and qualitative interviews that operationalized critical illness through ICU or high-dependency unit admission. Because admission thresholds, bed availability, and staffing models vary widely across settings, ICU or high-dependency unit admission is an imperfect marker of critical illness. As such, this is acknowledged as a study limitation. Future work should prioritize conceptual and operational definitions anchored in organ support and physiological need rather than location alone.

Representation of HSUs from LMIC was limited. Language and accessibility likely influenced both initial participation and retention. All study materials were in English, which may have introduced selection bias toward English-speaking participants and higher resource settings. Only two HSUs (both from North America) participated in small group discussions, and none attended the final consensus meeting. Several participating HCPs had trained, practiced, or originated from LMIC settings and provided important contextual insights, but these cannot substitute for lived experience. Although participants were encouraged to consider perspectives from lower resource settings, this is not an adequate mitigation strategy, and this limitation may reduce the cultural relevance and applicability of the COS in LMIC contexts. Future COSCO efforts should include intentional LMIC recruitment, multilingual and culturally adapted materials, and partnerships with local patient organizations.

The COMET methodology, while widely endorsed for COS development, has known limitations,[13,24] including participant burden,[25] attrition,[26,27] and potential disagreement about the final outcome set.[28,29] In this study, attrition between Delphi rounds was 35.3%. Although consistent with other Delphi studies, this attrition may have introduced bias if the perspectives of those who withdrew differed meaningfully from those who continued.[20] Demographic balance was monitored across rounds, but residual bias cannot be excluded and may have influenced which outcomes reached consensus.

Importantly, COSCO defines what should be measured, not how outcomes should be measured. Selecting appropriate

measurement instruments remains a critical next step.[30] Some outcomes, although important, were classified as noncore due to challenges in measurement and feasibility. For example, maternal quality of life is a key concern but lacks a universally accepted assessment tool, and the optimal timing of measurement varies. Similarly, long-term neurodevelopmental, cognitive, and psychological outcomes for neonates are widely recognized as essential but require extended follow-up, which may not be feasible in all settings, particularly in low-resource environments. These challenges highlight the need for validated contextually adaptable measurement tools that can be feasibly implemented across diverse settings. Researchers are encouraged to consult current definitions and measurement standards from professional organizations and consensus guidelines to ensure consistency. Recent guidance on reporting fetal and neonatal outcomes for non-obstetricians offers a promising model and may serve as a template for standardizing maternal and neonatal outcome measurement approaches.[31] Addressing these methodological gaps is essential to ensuring that outcomes prioritized by COSCO are not only identified but also consistently and meaningfully assessed in future research.[30]

5 | CONCLUSION

COSCO provides a standardized, consensus-based framework for outcome reporting in research on critically ill obstetric patients. By establishing a set of core outcomes, reporting checklist items, and important noncore outcomes, COSCO promotes consistency, improves comparability across studies, and strengthens the foundation for evidence synthesis. Its adoption is expected to improve the quality and impact of future research and inform the development of patient-centered clinical guidelines. Researchers are encouraged to implement COSCO to support high-quality, harmonized outcome reporting, and advance evidence-based care for individuals experiencing critical illness.

AUTHOR CONTRIBUTIONS

Tiffany Yeretsian: Data curation, Formal analysis, Investigation, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review and editing. **Julien Viau-Lapointe:** Conceptualization, Methodology, Writing – review and editing. **Rizwana Ashraf:** Software, Writing – review and editing. **Rohan D'Souza:** Conceptualization, Methodology, Supervision, Visualization, Writing – review and editing. **Stephen E. Lapinsky:** Conceptualization, Funding acquisition, Methodology, Supervision, Writing – review and editing.

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DATA AVAILABILITY STATEMENT

Research data are not shared.

ETHICS STATEMENT

Ethics approval was obtained from the Institutional Research Ethics Boards at Mount Sinai Hospital, Toronto, Ontario, Canada (Protocol #17-0238-E) on September 29 2017. Written informed consent was obtained from all participants prior to participation in the Delphi surveys and small group discussions.

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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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