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Development and Content of Core Outcome Sets in Neonatology—A Scoping Review

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ABSTRACT

Aim: To identify subgroups of neonates for whom core outcome sets (COS) have been developed, the outcomes that were included and the methods used in their formulation.

Methods: We performed a scoping review and searched databases in April 2025 for published COS. We included COS that reported neonatal outcomes, even when the original interventions targeted pregnant individuals. Methods of COS development and the included outcomes were extracted for descriptive analysis.

Results: A total of 363 abstracts were screened and 34 COS studies included for analysis. The most used methods were modified Delphi and Delphi consensus methods, consisting of a median of three rounds and a consensus meeting. Overall, a total of 62 distinct neonatal outcomes were proposed. The five most commonly included outcomes were neonatal mortality, preterm birth, birth weight, need for neonatal intensive care unit admission and neurodevelopment.

Conclusion: We found that the neonatal core outcome sets had clear heterogeneity in their selected outcomes. Future primary studies and evidence reviews should aim to focus on including important outcomes, when possible, to improve consistency in reporting.

Protocol Registration: Protocol was registered to open science framework and is available from https://osf.io/yngbd/.

1 | Introduction

Clinical trials seek to identify safe and effective therapies by analysing outcomes that are important to patients, families and health care professionals. The variability in reported outcomes across clinical trials and observational studies presents a major challenge to synthesising evidence and translating findings into clinical practice. The COMET initiative was launched to improve reporting by developing core outcome sets (COS) [1]. COS offer a standardised approach to outcome selection and reporting, ensuring that studies measure and report outcomes that are relevant, comparable, and meaningful to clinicians, researchers, and families [2–5]. Overall, the uptake of COS to clinical studies has been inconsistent [6].

In neonatal studies, the use of COS is especially important due to the diverse nature of neonatal morbidities and the long-term implications of early-life interventions. Furthermore, the outcomes measured in clinical studies have not always aligned with those most valued by families [7]. Examples include cranial ultrasound findings with unclear long-term significance and the need for supplemental oxygen at a single time-point (e.g.,

Abbreviations: COS, core outcome set; NICU, neonatal intensive care unit.

Summary

- There has been a rapid increase in the rate of published core outcome sets for neonates, and an overview of these was needed.
- We found 34 different core outcome sets consisting of 64 different neonatal outcomes, of which the most proposed outcomes were mortality, preterm birth and birth weight.
- Incorporating these outcomes in future studies will standardise reporting.

36 + 0 weeks of gestation). An overall COS for neonatal intensive care unit care in high-income countries was developed and published in 2020 and included 12 outcomes: survival, sepsis, necrotising enterocolitis, brain injury on imaging, general gross motor ability, general cognitive ability, quality of life, adverse events, visual impairment/blindness, hearing impairment/

TABLE 1 | Characteristics of the included core outcome set development studies.

	N
Target	
Neonate	10
Parturient and neonate	24
Method used	
Delphi	13
Modified Delphi	19
Other	2
***N* of Delphi rounds**	
Median + IQR	3 (2–3)
***N* of participants**	
Median + IQR	128 (82–221)
Stakeholders included in the process	
Neonatologists	32
Other healthcare professionals	30
Parents	32
Researchers	27
Systematic review performed	
Yes	33
No	1
Consensus meeting held	
Yes	34
No	0
***N* of core outcomes**	
Median + IQR + range	8 (5–12; 4–19)

TABLE 2 | Core outcome sets classified into subgroups based on the topic.

Congenital/fetal structural or placental disorders	Maternal medical disorders (pre-existing or pregnancy-specific)	Placental or fetal-growth complications	Neonatal diseases & syndromes	Care-process/preventive & public-health topics	Adverse perinatal outcomes & metrics
Hirschsprung disease	Epilepsy in pregnancy	Pre-eclampsia	Necrotizing enterocolitis	Overall maternal care	Stillbirth
Gastroschisis	Gestational diabetes	Reduced fetal movement	Neonatal encephalopathy	Labour induction	Neonatal outcome overall
Congenital diaphragmatic hernia	Pregestational diabetes	Fetal growth restriction	Neonatal sepsis	Labour care overall	
Fetal urinary tract obstruction	Hyperemesis gravidarum	Selective fetal growth restriction	Neonatal growth restriction	Prenatal care visits	
Twin-to-twin transfusion syndrome	Opioid withdrawal in pregnancy			Pregnancy nutrition	
Vasa previa	Endometriosis in pregnancy			Pregnancy outcome overall	
	Pregnant women with multimorbidity			Epidemic threats for mothers and neonates	
				Miscarriage prevention	
				Stillbirth prevention	
				Preterm birth prevention	

deafness, retinopathy of prematurity and chronic lung disease/bronchopulmonary dysplasia [8]. COS for specific health issues including pre-eclampsia, congenital abnormalities and neonatal sepsis have been published in recent years [9–11].

The aim of this scoping review was to identify neonatal patient groups for whom COS have been developed. Secondary aims included the identification of the outcomes which were included and the processes by which these COS were developed.

2 | Methods

2.1 | Study Selection Process

For this scoping review, we searched PubMed (MEDLINE), Web of Science and Scopus databases on April 1, 2025. The complete search strategy is provided in the Supporting Information. The search results were uploaded to Covidence software for screening. Two authors (IK and MH) independently screened the abstracts. Disagreements were resolved by consensus initially, with resolution using a third author (PK) when required. Two authors (IK and PK) screened the full reports in a similar manner. The reference lists of included articles were searched for additional eligible articles. We did not search the grey literature (conference abstracts and other non-peer reviewed publications).

2.2 | Inclusion Criteria

We included all consensus studies developing core outcome sets for neonates regardless of the methodology. We defined a neonate as an infant less than 28 days of age. The COS study was included if it had clear domains relevant to the newborn infant. Thus, studies in which the primary aim was to assess maternal health or complications during pregnancy, but which reported neonatal outcomes, were included. We excluded studies which did not clearly develop a COS. For example, studies that described outcomes of published trials or conducted interviews on outcome importance, but did not present clear COS, were excluded.

2.3 | Outcomes

We sought to identify (1) clinical scenarios for which COS were developed and (2) the most common proposed outcomes. We used descriptive statistics to characterise the COS, the methods used to develop them, and the participants who were included in the process.

2.4 | Data Extraction

Two authors screened abstracts and full text articles. Covidence software was used in the screening and extraction process. In cases of disagreement, the two reviewers sought consensus. A third reviewer was used in cases of persisting disagreements. Two authors (IK and MH) performed data extraction independently. The following information was extracted: authors, year of publication, outcome set development methods, participants and results.

This study has been reported according to the Preferred Reporting Items in Systematic Reviews and Meta-Analyses—Scoping Review extension guideline [12].

2.5 | Protocol

The protocol was prospectively published in Open Science Framework and is available from: https://osf.io/yngbd/.

3 | Results

A total of 34 publications, published between 2016 and 2025, were included in the final analysis [8–11, 13–42]. (Figure S1) They used mostly modified Delphi and Delphi consensus methods, and the median number of rounds was three (IQR 2–3) (Table 1) All but one of the COS were based on a systematic literature search to identify possible outcomes, and all 34 COS held official final consensus meetings. The median number of participants was 128. All the studies that reported the participant characteristics included neonatologists and parent representatives (Table 1).

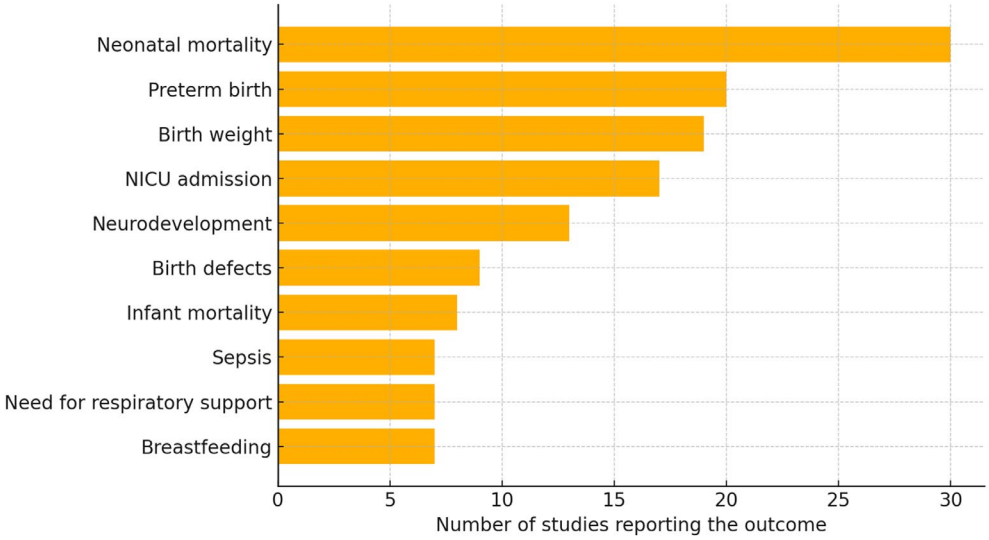

FIGURE 1 | The 10 most common outcomes included in the 34 core outcome sets.

TABLE 3 | Outcomes classified into thematic subgroups.

Survival & mortality	Birth status	Neurologic outcomes	Respiratory outcomes	GI/nutrition/ metabolic/ hepatic	Renal	Infectious outcomes	Sensory outcomes	Healthcare use & interventions	Miscellaneous	Surgical safety
Neonatal mortality	Preterm birth	Hypoxic-ischaemic encephalopathy (HIE)	Need for respiratory support	Necrotising enterocolitis (NEC)	Kidney replacement therapy	Sepsis	Retinopathy of prematurity (ROP)	NICU admission	Quality of life	Need for unplanned reoperation
Infant mortality	Birth weight (includes SGA and LGA)	Seizures	Broncho-pulmonary dysplasia (BPD)	Need for gastrointestinal surgery	Need for renal surgery	Central-nervous-system infection	Visual impairment	Admission duration	Parent-infant bonding	Number of operations
	Birth height	Intraventricular haemorrhage (IVH)	Pulmonary hypertension	Short-bowel syndrome	Renal transplant	Vertical transmission of infection	Hearing impairment	Readmission after discharge	Skin-to-skin contact	Severe complication
	Birth defects	Periventricular leukomalacia (PVL)	Pulmonary hypoplasia	Feeding difficulties	Chronic kidney disease (CKD)	Multiorgan dysfunction		Adverse events overall	Consolability	Neonatal blood loss
	Apgar scores	Brain injury on imaging	Meconium aspiration syndrome	Liver disease					Postnatal growth	
	Acidemia pH < 7.0 or BE > 16	Neurological status	Need for ECMO	Time on parenteral nutrition					Neonatal withdrawal symptoms	
	Birth injury	Cerebral palsy		Breastfeeding					Disease-specific long-term outcomes	
	Resuscitation at birth	Neurodevelopment		Hypoglycaemia					Total opioid dose	
	Need for therapeutic hypothermia	Fetal anticonvulsant syndrome							Time to symptom control	

The majority of the reports encompassed both mothers' and infants' outcomes ($n = 24$), reflecting that most interventions took place during pregnancy. The 34 COS included and covered six separate themes (Table 2). Some of the COS were extremely specific, such as vasa previa or twin-to-twin transfusion syndrome COS, whereas there were COS for overall pregnancy, labour and neonatal outcomes (Table 2). These 34 COS proposed a total of 62 distinct neonatal outcomes (Table S1). The median number of proposed outcomes per COS was eight, ranging from four to nineteen (Table 1) The most common outcomes were neonatal mortality, preterm birth, birth weight and NICU admission (Figure 1) The main themes for outcomes are presented in Table 3.

4 | Discussion

This scoping review identified 34 COS that included outcomes for neonates. The most commonly proposed outcomes were neonatal mortality, preterm birth, birth weight, NICU admission and neurodevelopment.

In 2020, an overall COS for neonatal care in high-income countries proposed 12 core outcomes. Interestingly, the four stakeholder groups (patients and parents, nurses and therapists, doctors, and researchers) all ranked three outcomes (mortality, necrotizing enterocolitis, and sepsis) in their top four [8]. Unfortunately, the majority of the other included COS did not report the outcome rankings by stakeholder group, which would have been valuable for evaluating potential differences in preferences. A previous study has found that parents of neonates may rank outcomes differently than clinicians [43]. A more recent survey found that parents valued quality of life measures higher than health complications [44].

The aim of a core outcome set is to improve the standardisation of outcomes selected for future studies and systematic reviews. However, a persisting challenge in neonatal research is the lack of consistent outcome definitions, which reflects both the complexity of neonatal conditions and the ongoing development of clinical understanding and consensus [45]. Many of the presented outcomes presented in the included COS were either overly broad—such as 'adverse events', or 'quality of life', which can be assessed using various methods—or inconsistently defined, as in the case of bronchopulmonary dysplasia and sepsis [46, 47]. Some COS addressed this issue by also providing explicit definitions and recommended measurement tools to enhance clarity and comparability [42].

As all the COS included were based on the COMET initiative, the methods were comparable. The majority used outcomes extracted from published studies and conducted a Delphi or a modified Delphi process consisting of 2–3 rounds followed by a final consensus meeting. Parents were included in the COS process in all studies, and the majority also had other stakeholders such as researchers, policy makers, and regulators involved. A key challenge for COS initiatives has been that, despite the increasing number of published sets, their consistent implementation in clinical research and practice remains limited [6].

5 | Strengths and Limitations

The main strength was the systematic search and data extraction process which improved the reliability of this study. The main limitation is the lack of comparison of what were important outcomes for the different stakeholder groups, as the studies included rarely separated the results for these groups. Future COS studies should report results stratified by these subgroups in order to better understand the relative importance of different outcomes to different stakeholders.

6 | Conclusion

We found that the neonatal core outcome sets were heterogeneous in terms of development and selected outcomes. The COS mostly used a modified Delphi process with 3 rounds and consensus meetings. The most proposed core outcomes were neonatal mortality, gestational age, birth weight, and need for NICU admission. Future studies and reviews should focus on including outcomes that are important to clinicians and families in order to improve the consistency and relevance of the reporting.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.