

Core outcome sets for research within the area of maternity care

Overview of completed and ongoing studies

Background

When research is synthesised in systematic reviews it becomes clear that studies often overlook outcomes of importance to patients and that different outcomes as well as different methods or timepoints are used when assessing outcomes. This detracts from the potential to synthesise the results of different studies and as a result, the scientific evidence to support many treatment procedures is weakened. It is important that clinical studies use outcomes which are meaningful when patients and healthcare personnel are to make a decision, for example about type of treatment.

A core outcome set (COS) is an agreed standardised set of outcomes that should be assessed and reported, as a minimum, in all clinical trials in specific areas of health or health care (Figure 1). The outcomes to be included in different COS are selected by a consensus process in which healthcare personnel, researchers and patients should be included [1]. The aim with developing and implementing COS is that the results from various studies can be more readily comparable and collated, so that the basis for decisions, for patients and healthcare personnel, is therefore strengthened.

The main target groups for the report are researchers and research funders. The findings may also be of interest to professional associations, organizations and

units involved in maternity/obstetric care. The project has been commissioned by the Swedish government, as part of its efforts for the promotion of women's health.

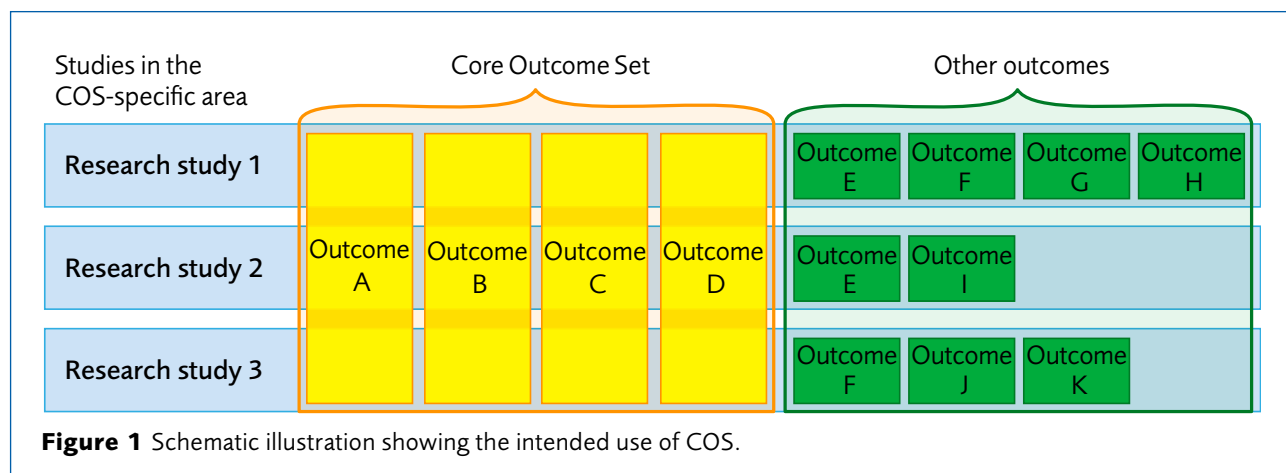
Aim

The aim is to inventory, compile and analyse existing and ongoing studies which prioritize core outcomes within the field of maternity care (so-called Core Outcome Set (COS)). The report also highlights fields of potential interest for production of new COS, based on the opinions of patients, researchers and healthcare personnel.

Method

In order to identify completed and ongoing COS in the field of maternity care, a search of the literature was conducted (Appendix 1), followed by a summary of studies in the field.

We have also investigated how well the identified COS studies fulfil the proposed reporting criteria, using a checklist modified after Core Outcome Set–STAndards for Reporting (COS-STAR) (Appendix 2) [2]. In order to gain an indication of topics for which there may be a demand for new COS, an open questionnaire was posted on SBU's website. This allowed relevant interested parties (primarily patients and their relatives, healthcare personnel and research-



ers) to nominate fields within maternal health which they considered warranted a COS.

The protocol is registered in Prospero and the COMET initiative database.

Inclusion criteria

Population

- Pregnant women
- Women giving birth (labour and delivery)
- Women who suffer an injury or other complication related to childbirth
- Women or men suffering from psychiatric disorder during pregnancy or during or after childbirth

Intervention

No restriction.

Control

Not applicable.

Outcome

A list of outcomes included in the COS.

Study design

Ongoing or finalized original studies were outcomes were prioritized using some form of consensus method.

Language

English and Scandinavian languages.

Search period

Final search, June 2019.

Databases searched

MEDLINE, Embase, PsycINFO, Academic Search Elite, CINAHL with Full Text, SocINDEX with Full Text and the Core Outcome Measures in Effectiveness Trials (COMET) Initiative database.

Client/patient involvement

Yes

Results

This report identified 19 completed studies which prioritized outcomes, Table 1, Table 2 and Table 3.

Among these, the main aim for 12 was to develop a COS for future research [3–14]. In the remaining seven studies, outcomes were also prioritized, but the main aim of the studies somewhat varied [15–21]. The primary aim of two articles was to prioritize future research questions, and this included prioritizing the outcomes to be assessed [15,21]. Two other articles investigated which outcomes should be prioritized in a composite outcome while other studies considered which outcomes should be assessed in clinical follow-up of patients [16–20]. Of the 19 studies identified, nine met the reporting criteria for COS-studies well [3,4,7–10,12–14]. In addition to these studies, 39 COS-studies in progress were identified: for ten of these, protocols were published (Appendix 4) [22–31].

Most of the COS-studies identified (both completed and ongoing) focused on physical conditions and complications during pregnancy. There was also several COS for different preventive measures during pregnancy.

The result show that COS exist or are under development for many of the specified conditions highlighted by SBU's open questionnaire, for example gestational diabetes, preeclampsia, maternal birth injuries, miscarriage and stillbirth. The results disclose however a lack of existing COS or COS under development, for mental health problems or mental illness during or after pregnancy.

Discussion

In the research fields of women's health and neonatal health, an international network, called CoRe Outcomes in Women's and Newborn health (CROWN), has been established [32]. It is led by journal editors, and aims to address the widespread, unwarranted variation in reporting of outcomes, which makes comparison between and combination of results across studies difficult, if not impossible. As a result, there is currently considerable activity in the development of various COS in the field of maternity care.

It is however important to point out that there remain many important subfields within obstetrics/childbirth where there are no COS. This applies for example to vaginal delivery and caesarean section, topics nominated in SBU's questionnaire, primarily by healthcare personnel and researchers. Other fields which completely lack existing COS or COS under development are mental health issues or illness during pregnancy and after childbirth.

COS is a relatively new concept in the world of research. This is the first time SBU has presented an overview of completed and ongoing COS. The aim is that this report shall contribute to dissemination of knowledge about what a COS is, which COS are established within maternal health and which are under development. Moreover, the report can contribute to increasing the potential for Swedish researchers to apply existing COS and to participate in development of COS developed by international actors. As an HTA-organisation, SBU supports the

use of COS: in the long term, COS can contribute to scientific evidence of higher certainty. For a COS to be implemented effectively, SBU believes that it is important to discuss how broad the field, for which the COS applies, should be, and how many outcomes can be included in a practically applicable COS. Moreover, it is important to continue to work with various instruments in order to appraise the methodology of established COS and the representativity of the stakeholders who participated in the consensus process.

Table 1 Description of included completed COS studies.

Ref First Author Year	Population Intervention Setting	Stakeholders represented in the workgroup	Consensus criteria for an outcome to be included in the final COS	Method used Participants receiving the first survey, % of participants answering all surveys, participants at consensus meeting
[10] Meher 2018	Postpartum haemorrhage Two core outcomes sets presented one for prevention and one for treatment Clinical trials	Healthcare professionals and women's representatives from 36 nations Sweden not represented	At least 70% of participants in each stakeholder group to score the outcome as critically important and <15% to score the outcome as not important	A two-round Delphi survey and face-to-face consensus meeting Prevention: 205, 74%, 36 Treatment: 197, 73%, 36
[19] Nijagal 2018	Women and infants The care that they receive during pregnancy and the postpartum period	Consumer representatives and international experts in various fields of perinatal and neonatal care, research and patient advocacy from 8 nations. One person from Sweden included	Outcome domains thought to be "critical" (scored between 7 and 9) by at least 70% of the respondents were included in the set	A series of nine teleconferences, incorporating a modified Delphi process 21, 73%, NA
[16] Bunch 2018	Women in maternity care Monitor the quality of maternity care	Service designers, providers and users from England	≥70% of participants rated the metric 7–9 (high importance) and <15% rated it as 1–3 (low importance)	A two-round Delphi survey and face-to-face consensus meeting 101, 71%, 19
[8] Egan 2017	Women with pregestational diabetes Prepregnancy care Clinical trials	Clinicians' patient's policy makers, researchers in the area advocates on behalf of those with diabetes and others from 24 nations. Do not specify which nations that were represented.	At least 70% of participants to score the outcome as critically important (7–9) and <15% to score the outcome as not important (1–3)	A three-round Delphi survey and face-to-face consensus meeting 151, 67%, 14
[14] Van 't Hooft 2016	Pregnant women Interventions to Prevent Preterm Birth Clinical trials	Parents, midwives, obstetricians, neonatologists, and re-searcher from 25 nations. Do not specify which nations that were represented.	Core outcomes required at least 70% of participants in each stakeholder group to score the outcome as "critical" and less than 15% of participants in each stakeholder group to score the outcome as limited importance.	A two-round Delphi survey and face-to-face consensus meeting 228, 76%, 29

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Table 1 continued

Ref First Author Year	Population Intervention Setting	Stakeholders represented in the workgroup	Consensus criteria for an outcome to be included in the final COS	Method used Participants receiving the first survey, % of participants answering all surveys, participants at consensus meeting
[6] Devane 2007	Models of maternity care Clinical trials	Healthcare professionals and women's representatives from 28 nations. Four participants from Sweden.	Outcomes with both a mean value greater than the overall group mean for all outcomes combined and rated 4 or more on a 5-point Likert-type scale for importance of inclusion in a minimum data set of outcome measures by at least 70% of respondents	A three-round Delphi survey 320, 48%, NA
[3] Al Wattar 2016	Epilepsy in pregnancy Clinical trials	Healthcare professionals, and patient representatives with lived experience of epilepsy from United Kingdom	We included outcomes that scored ≥ 4 by $>70\%$ of participants, and outcomes that scored ≤ 2 by $<15\%$ of participants (used a 5-point scale)	A modified three-round Delphi survey and consultation meeting 99 participants finished first survey, 49%, 15
[7] Dos Santos 2018	Pregnant women Induction of labour Clinical trials	Midwives, obstetricians, neonatologists, and women's representatives Number of nations not clearly stated	$\geq 70\%$ participants rated outcomes as critical and $<15\%$ rated outcomes as limited importance	A two-round Delphi survey and face-to-face consensus meeting 159, 45%, 20
[5] Briscoe 2019	Caesarean deliveries with infectious morbidity outcome Clinical trials	Systematic review authors Number of nations not clearly stated	Consensus of the panel was defined by the majority of respondents.	A two-round Delphi survey 41, 34%, NA
[18] Fong 2014	Late-onset preeclampsia Management Maternal and neonatal composite outcomes for trials	Practising senior clinicians and clinical academics from the United Kingdom	We selected the outcomes that had a median score of 4 or more and indicated consensus (IQR ≤ 2) for evaluation in the third stage. (5-point scale)	A two-round Delphi survey 44, 90% maternal outcomes 75% neonatal outcomes, NA
[15] Bennett 2012	Gestational Diabetes Mellitus Medication and delivery management Clinical trial	Clinical experts Number of nations not clearly stated	Appearing in the top 3 list of two or more of the nine national stakeholders	Regarding prioritization of outcomes, one- survey 20, NA, NA
[20] Rogozinska 2016	Pregnancy Diet and lifestyle Composite outcomes for individual patient data (IPD) meta-analysis	Researchers from the International Weight Management in Pregnancy collaborative network from 11 nations. Sweden not represented	Considered to be critically important by the Delphi panel (score >7), of equal importance, similar rates of occurrence, independent of each other, and evidence of the same trend in effect of the intervention	A two-round Delphi survey 26, 96%, NA

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Table 1 continued

Ref First Author Year	Population Intervention Setting	Stakeholders represented in the workgroup	Consensus criteria for an outcome to be included in the final COS	Method used Participants receiving the first survey, % of participants answering all surveys, participants at consensus meeting
[21] Saldanha 2013	Gestational diabetes mellitus Antenatal drug treatment	Clinicians, primary researchers, research funders, insurers, and patients or patient representatives from 1 nation	Not specified	Prioritization of research questions using the Delphi method for some including prioritization of outcomes. Does not specified how many rounds for outcomes. 9 participants
[17] Fiala 2018	Pregnancy First trimester medical termination	Group of European experts, included clinicians, researchers and members of the pharmaceutical industry Number of nations not clearly stated	Not specified	Face-to-face consensus meeting Number of participants not clearly stated
[4] Bogdanet 2019	Women with gestational diabetes treated with insulin and/or oral glucose-lowering agents Follow-up at 1 year and beyond Clinical trails	Patients, clinicians, researchers, policy makers and others from 33 nations. Participants from Sweden included.	At least 70% of participants to score the outcome as critically important (7–9) and <15% to score the outcome as not important (1–3)	A three-round Delphi survey and face-to-face consensus meeting 835, 20%, 20
[11] Mehra 2012	Pregnancy weight management clinical trails (Only available as a conference abstract)	20 Consultants from 2 nations	Not enough information provided	A two-round Delphi survey 20 participants
[13] Townsend 2019	Selective fetal growth restriction in twins management clinical trails	Clinicians, obstetricians, fetal medicine specialists, neonatologists, and midwives), researchers, and parents or patients from 23 nations. Do not specify which nations that were represented.	Consensus was defined as any outcome achieving a median score of eight after the third round. All outcomes meeting this criterion were taken forwards as potential core outcomes for discussion	A three-round Delphi survey and face-to-face consensus meeting using the modified nominal group technique 102 participants completed first survey, 86%, 19
[12] Perry 2019	Twin – twin transfusion syndrome (TTTS) treatments	Healthcare professionals, researchers and patients or relatives of patients who had experienced TTTS from 29 nations. Do not specify which nations that were represented.	Defined a priori using the 15% / 70% definition of the COMET initiative.	A three-round Delphi survey and face-to-face consensus meeting using the modified nominal group technique 103 participants completed first survey, 85%, 16
[9] Healy 2019	Fetal growth restriction prevention and treatment	Healthcare providers, researchers/academics, members of the public from 36 nations. Do not specify which nations that were represented.	At least 70% of participants to score the outcome as critically important (7–9) and <15% to score the outcome as not important (1–3)	A three-round Delphi survey and face-to-face consensus meeting 238, 45%, not specified

NA = not applicable; IQR= interquartile range; TTTS = Twin – twin transfusion syndrome

Table 2 Outcomes included in the final COS for the identified studies and to what degree the studies complied with COS-STAR.

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
[10] Meher 2018 Prevention and treatment of postpartum haemorrhage	Prevention of postpartum haemorrhage: <ul style="list-style-type: none"> • Blood loss • Shock • Maternal death • Use of additional uterotonics • Blood transfusion • Transfer for higher level of care • Women's sense of wellbeing • Acceptability and satisfaction with the intervention • Breastfeeding • Adverse effects 	Good compliance with COS-STAR Not able to access protocol
<i>Continued</i> [10] Meher 2018 Prevention and treatment of postpartum haemorrhage	Treatment of postpartum haemorrhage: <ul style="list-style-type: none"> • Blood loss • Shock • Coagulopathy • Hysterectomy • Organ dysfunction • Maternal death • Blood transfusion • Use of additional haemostatic intervention • Transfer for higher level of care • Women's sense of wellbeing • Acceptability and satisfaction with the intervention • Breastfeeding • Adverse effects 	

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Table 2 continued

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
[19] Nijagal 2018 Care for women and infants during pregnancy and the postpartum period	<ul style="list-style-type: none"> • Maternal death • Still birth • Neonatal death • Maternal need for intensive care • Maternal length of stay • Late maternal complication • Transfusion • Spontaneous preterm birth • Iatrogenic preterm birth • Oxygen dependence • Neonate length of stay • Birth injury • Health related quality of life • Incontinence • Pain with intercourse • Success with breastfeeding • Confidence with breastfeeding • Mother-infant attachment • Confidence with role as a mother • Postpartum Depression • Satisfaction with the results of care • Confidence as an active participant in healthcare decisions • Confidence in healthcare providers • Birth Experience 	<p>Some details form COS-STAR not reported</p> <p>No reference to a protocol given.</p> <p>Only 2 consumers and 19 clinical expertise in the working group</p> <p>A very large number of outcomes included in the final COS</p>
[16] Bunch 2018 Monitor the quality of maternity care	<ul style="list-style-type: none"> • Smoking rate at booking • Rate of birth without intervention • Caesarean section delivery rate in Robson group 1 women • Caesarean section delivery rate in Robson group 2 women • Caesarean section delivery rate in Robson group 5 women • Third-and fourth-degree tear rate among women delivering vaginally • Rate of postpartum haemorrhage of ≥ 1500 ml • Rate of successful vaginal birth after a single previous caesarean section • Smoking rate at delivery • Proportion of babies born at term with an Apgar score < 7 at 5 minutes • Proportion of babies born at term admitted to the neonatal intensive care unit • Proportion of babies re admitted to hospital at < 30 days of age • Breastfeeding initiation rate • Breastfeeding rate at 6–8 weeks 	<p>Some details form COS-STAR not reported</p> <p>No reference to a protocol given</p> <p>Patients are included in the panel but not represented at the final meeting</p>

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Table 2 continued

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
[8] Egan 2017 Pregnancy care for women with pregestational diabetes	<ul style="list-style-type: none"> • Healthcare professional review prior to conception • Smoking status at first antenatal visit • Use of folic acid preconception • Thyroid function at first antenatal visit • Use of potentially teratogenic medications at conception • Gestational age at first antenatal visit • BMI at first antenatal visit • BP at first antenatal visit • First trimester HbA1c • Perinatal mortality • Miscarriage • Congenital malformation • Preterm birth • Large for gestational age • Small for gestational age • Gestational weight gain • Severe maternal hypoglycaemia in first trimester 	<p>Good compliance with COS-STAR</p> <p>Does not specify the number of non-responders from the first survey.</p> <p>Only a few patient representatives present in the workshop</p>
[14] van 't Hooft 2016 Interventions to Prevent Preterm Birth	<p>Related to pregnant women:</p> <ul style="list-style-type: none"> • Maternal mortality • Maternal infection or inflammation • Prelabor rupture of membranes • Harm to mother from intervention <p>Related to offspring:</p> <ul style="list-style-type: none"> • Gestational age at birth • Off-spring mortality • Birth weight • Early neurodevelopmental morbidity • Late neurodevelopmental morbidity • Gastrointestinal morbidity, infection • Respiratory morbidity • Harm to offspring from intervention 	<p>Good compliance with COS-STAR</p> <p>Only a few patient representatives present in the workshop</p>

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Table 2 continued

Ref	Final COS	Compliance with COS-STAR
First author		Comments
Year of publication		
Subject		
[6] Devane 2007 Models of maternity care	<ul style="list-style-type: none"> • Maternal death • Mode of birth • Neonatal death • Stillbirth • Type of labour onset • Neonatal admission to special care and/or intensive care unit • Birth injury to infant • Ruptured uterus • Postpartum haemorrhage • Mother requires admission to intensive care • Maternal postnatal readmission to hospital • Method of infant feeding • Vaginal birth after previous caesarean section • Gestational age at birth • Postnatal depression • Place of birth • Neonatal resuscitation required • Normal (i.e., physiological) birth without intervention • Oxytocin augmentation of labour • Anal sphincter damage • Hypoxic ischemic encephalopathy (a condition of injury to the brain) • Intrapartum hypertensive disorders of pregnancy • Hypertensive disorders of pregnancy • Puerperal psychosis • Maternal fecal incontinence • Neonatal readmission to hospital • Apgar score at 5 min • Trial of labour after previous caesarean delivery • Breastfeeding at 3 months • Maternal satisfaction (postnatal) • Infant birthweight • Neonatal fitting/seizures • Infant requiring intubation • Congenital anomaly (chromosomal, genetic, and/or structural) • Use of pharmacological analgesia/anesthesia • Maternal satisfaction (antenatal) • Postnatal hypertensive disorders of pregnancy • Maternal satisfaction (intrapartum) • Caesarean section wound infection • Pulmonary embolism • Intrauterine growth restriction • Preterm labour • Meconium aspiration 	<p>Some details form COS-STAR not reported</p> <p>No reference to a protocol given</p> <p>The PICO for the COS is not clearly stated</p> <p>Very broad area for the COS development and a very large number of outcomes included in the final COS.</p>

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Table 2 continued

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
<i>Continued</i> [6] Devane 2007 Models of maternity care	<ul style="list-style-type: none"> • Intrapartum haemorrhage • Neonatal infection • Shoulder dystocia • HELLP = hemolysis, elevated liver enzymes, and low platelets • Birth asphyxia • Breastfeeding at discharge 	
[3] Al Wattar 2016 Epilepsy in pregnancy	<p>Maternal</p> <ul style="list-style-type: none"> • Seizure control in pregnancy • Postpartum seizure control • Status epilepticus • Maternal mortality • Drowning • Sudden unexpected death in epilepsy • Postnatal depression • Maternal quality of life • Maternal anti-epileptic drug toxicity • Compliance with anti-epileptic drug intake <p>Offspring outcomes</p> <ul style="list-style-type: none"> • Major congenital abnormalities • Minor congenital abnormalities • Fetal anticonvulsant syndrome • Neurodevelopment • Autism spectrum disorder • Neonatal clinical complications • Admission to neonatal intensive care unit • Anthropometric measurements, including birthweight • Neonatal withdrawal symptoms • Neonatal haemorrhagic disease <p>Obstetric outcomes</p> <ul style="list-style-type: none"> • Live birth • Stillbirth • Miscarriage • Ectopic pregnancy • Termination of pregnancy • Maternal admission to high dependency or intensive care unit • Breastfeeding • Mode of delivery • Preterm birth • Pre-eclampsia • Eclampsia 	<p>Good compliance with COS-STAR</p> <p>Patients participated in a separate survey which consisted of only one round</p> <p>Only persons from United Kingdom represented</p> <p>A very large number of outcomes included in the final COS</p>

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Table 2 continued

Ref	Final COS	Compliance with COS-STAR
First author		Comments
Year of publication		
Subject		
[7] Dos Santos 2018 Induction of labour	<p>Short-term maternal outcomes</p> <ul style="list-style-type: none"> • Cardiorespiratory arrest • Damage to internal organs • Death • Haemorrhage • Hysterectomy • Infection • Intensive care admission • Length of hospital stay • Mode of delivery • Need for more than one induction agent • Oxytocin augmentation • Postnatal depression • Pulmonary embolus • Satisfaction with care • Stroke • Time from induction to delivery • Uterine hyperstimulation • Uterine scar dehiscence/rupture <p>Short-term offspring outcomes</p> <ul style="list-style-type: none"> • Admission to the neonatal unit • Birth trauma • Death • Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia • Meconium aspiration syndrome • Need for respiratory support • Infection • Seizures <p>Long-term maternal outcomes</p> <ul style="list-style-type: none"> • Operative pelvic floor repair <p>Long-term offspring outcomes</p> <ul style="list-style-type: none"> • Disability including neurodevelopmental delay 	<p>Good compliance with COS-STAR</p> <p>Only a few patient representatives present in the workshop</p> <p>A very large number of outcomes included in the final COS</p>
[5] Briscoe 2019 Caesarean deliveries with infectious morbidity outcome	<ul style="list-style-type: none"> • Endometritis (primary outcome) • Maternal mortality • Wound infection • Wound complications • Febrile morbidity • Neonatal morbidity 	<p>Significant details from COS-STAR not reported</p> <p>No reference to a protocol given</p> <p>Only includes authors of systematic reviews in the process</p>

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Table 2 continued

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
[18] Fong 2014 Composite outcomes regarding management late-onset preeclampsia	<p>The maternal composite outcome included</p> <ul style="list-style-type: none"> • Maternal death • Eclampsia • Stroke or reversible ischaemic neurological deficit • Pulmonary oedema • Major obstetric haemorrhage • Need for positive inotropic support • Haemolysis • Elevated liver enzymes and low platelets syndrome and placental abruption <p>The neonatal composite outcome included</p> <ul style="list-style-type: none"> • Neonatal death • Respiratory distress syndrome • Needing ventilator support and neurological outcomes as cystic periventricular leukomalacia and grade iii/iv intraventricular haemorrhage. 	<p>Significant details from COS-STAR not reported</p> <p>Aim is not a conventional COS development but a development of a composite outcome.</p> <p>No reference to a protocol given</p> <p>No patients included in the process</p>
[15] Bennett 2012 Medication and delivery management for Gestational Diabetes Mellitus	<ul style="list-style-type: none"> • Hypertensive disorders of pregnancy • Medication adherence • Large for gestational age and macrosomia • Gestational weight gain • Neonatal hypoglycemia • Neonatal intensive care unit admission • Chronic disease incidence in offspring • Postpartum incident type 2 diabetes mellitus or glucose intolerance/ impaired fasting glucose management • Cesarean delivery • Birth trauma • Neonatal intensive care unit admission • Patient-reported outcomes (e.g., patient preference, quality of life) • Complications of cesarean delivery (e.g., wound infection, wound dehiscence) • Vaginal delivery (spontaneous, operative) • Hypoxia/anoxia • Respiratory distress syndrome 	<p>Significant details from COS-STAR not reported</p> <p>The aim of the article is to prioritize research need. For some of the research questions the outcomes to measure were also prioritized.</p> <p>No patients included, but two members that served as proxy for the patient/ consumer perspective</p>
[20] Rogozinska 2016 Composite outcomes for diet and lifestyle interventions in pregnancy	<p>The maternal composite outcome included</p> <ul style="list-style-type: none"> • Pre-eclampsia/pregnancy induced hypertension • Gestational diabetes mellitus (GDM) • Elective or emergency caesarean section • Preterm delivery <p>The neonatal composite outcome included</p> <ul style="list-style-type: none"> • Intrauterine death • Small for gestational age • Large for gestational age • Admission to a neonatal intensive care unit 	<p>Significant details from COS-STAR not reported</p> <p>Aim is not a conventional COS development but a development of a composite outcome.</p> <p>No reference to a protocol given</p> <p>Only researchers included in the process</p>

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Table 2 continued

Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
[21] Saldanha 2013 Antenatal drug treatment for gestational diabetes mellitus	<p>Oral agents compared with insulin:</p> <ul style="list-style-type: none"> • Chronic diseases (e.g., obesity and type 2 diabetes) in the offspring • Hypertensive disorders of pregnancy (e.g., GDM and pre-eclampsia) in the mother • Large for gestational age • Macrosomia in the neonate <p>Selective cesarean delivery or the choice of timing of induction:</p> <ul style="list-style-type: none"> • Cesarean delivery (primary cesarean and repeat cesarean) • Indication for cesarean delivery in the mother • Birth trauma (e.g., bone fractures and cerebral palsy) • Neonatal intensive care unit admission 	<p>Significant details from COS-STAR not reported</p> <p>The aim of the article is to prioritize research need. For some of the research questions the outcomes to measure were also prioritized.</p> <p>No reference to a protocol given</p>
[17] Fiala 2018 First trimester medical termination	<ul style="list-style-type: none"> • Success • Failure (ongoing pregnancy) • Need for additional treatment (medical or surgical) to complete MToP (missed abortion, incomplete abortion) • Complications • The woman's request for additional treatment (medical or surgical) 	<p>Significant details from COS-STAR not reported</p> <p>The aim of the article is to standardize the definition of the outcomes</p> <p>No reference to a protocol given</p> <p>No Delphi survey</p>
[4] Bogdanet 2019 Follow-up at 1 year and beyond for women with gestational diabetes treated with insulin and/or oral glucose-lowering agents	<ul style="list-style-type: none"> • Assessment of glycaemic status • Diagnosis of type 2 diabetes since the index pregnancy • Number of pregnancies since the index pregnancy • Number of pregnancies with a diagnosis of GDM since the index pregnancy • Diagnosis of prediabetes since the index pregnancy • BMI • Post-pregnancy weight retention • Resting blood pressure • Breastfeeding 	<p>Good compliance with COS-STAR</p>
[11] Mehra 2012 Weight management interventions in pregnancy	<p>Top 5 clinically important outcomes:</p> <ul style="list-style-type: none"> • Gestational diabetes • Preeclampsia • Gestational hypertension • Maternal admission to ITU/HDU • Venous thromboembolism 	<p>Not able to check compliance with COS-STAR</p> <p>Conference abstract. Lot of information missing</p>
[13] Townsend 2019 Management of selective fetal growth restriction in twins	<ul style="list-style-type: none"> • Live birth • Gestational age at birth • Birth weight • Inter-twin birthweight discordance • Death of surviving twin after death of co-twin • Loss during pregnancy or before final hospital discharge (miscarriage, stillbirth, termination of the pregnancy, neonatal death, perinatal death) • Parental stress 	<p>Good compliance with COS-STAR</p> <p>Does not specify the number of non-responders from the first survey.</p>

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Table 2 continued

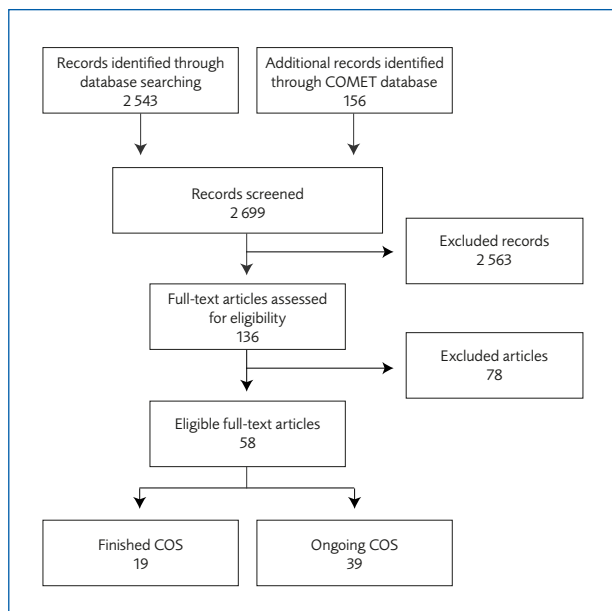
Ref First author Year of publication Subject	Final COS	Compliance with COS-STAR Comments
Continued [13] Townsend 2019 Management of selective fetal growth restriction in twins	<ul style="list-style-type: none"> • Procedure-related adverse outcome (failure of procedure, procedure to delivery interval, placenta abruption, life threatening haemorrhage, sepsis, maternal death) • Length of stay in hospital (neonatal) • Neurological abnormalities on postnatal imaging • Childhood disability 	
[12] Perry 2019 Twin – twin transfusion syndrome	<ul style="list-style-type: none"> • Live birth • Pregnancy loss (including miscarriage, stillbirth, termination of pregnancy and neonatal mortality) • Subsequent death of a cotwin following single-twin demise at the time of treatment • Recurrence of TTTS • Twin anemia – polycythemiasequence and amniotic band syndrome • Gestational age at delivery • Birthweight • Brain injury syndromes • Ischemic limb injury • Maternal mortality • Admission to Level-2 or -3 care setting • One aspirational outcome • Neurodevelopment at 18–24 months of age 	<p>Good compliance with COS-STAR</p> <p>Does not specify the number of non-responders from the first survey.</p>
[9] Healy 2019 Prevention and treatment of fetal growth restriction	<ul style="list-style-type: none"> • Preeclampsia • Eclampsia • Maternal death • Mode of birth • Fetal stillbirth/livebirth • Gestational age at birth • Preterm birth (delivery at <37 weeks gestation) • Extremely preterm birth (delivery at <28 weeks gestation) • Birthweight • Birthweight <10th percentile • Birthweight <3rd percentile • Need for mechanical ventilation • Bronchopulmonary dysplasia/chronic lung disease • Necrotizing enterocolitis • Neonatal seizures • Hypoxic ischemic encephalopathy • Neonatal death • Childhood cognitive impairment • Motor impairment • Cerebral palsy • Hearing Impairment • Visual Impairment 	<p>Good compliance with COS-STAR</p> <p>A very large number of outcomes included in the final COS</p>

BP = Blood pressure; BMI = Body Mass Index; COS = Core Outcome Set; COS-STAR = Core Outcome Set–STAndards for Reporting; GDM = Gestational diabetes mellitus; HbA1c = Hemoglobin A1c (Långtidsblodssockret); MToP = Medical termination of pregnancy; ITU/HDU = Intensive care units (/ high dependency units)

Tabell 3 Number of outcomes at start of prioritization and number of outcomes in final COS.

Ref First author	Number of outcomes in first round	Number of outcomes added by participants	Number of outcomes in final COS
[10] Meher	Prevention: 161 combined into 35 Treatment: 97 combined into 31	Prevention: 16 Treatment: 18	Prevention: 9 Treatment: 12
[19] Nijagal	Not specified	Not specified	24
[16] Bunch	125	19	14
[8] Egan	86	27	17
[14] Van 't Hooft	86 grouped into 29	2	13
[6] Devane	263	73	48
[3] Al Wattar	70 grouped into 48	Not enough information provided	31
[7] Dos Santos	93 reduced to 77 by combining different outcomes after first survey round	4	28
[5] Briscoe	511 Outcomes were grouped into 20 primary outcome groups	4	6
[18] Fong	21 maternal and 24 neonatal outcomes	8	Maternal composite outcome: 7 Neonatal composite outcome: 3
[15] Bennett	>20	NA	Medication management of GDM: 8 Delivery management for women with GDM: 8
[20] Rogozinska	Maternal: 36 Fetal and neonatal: 27	Maternal: 2 Fetal and neonatal: 2	Maternal: 6 (condensed to 4) Fetal and neonatal: 4
[21] Saldanha	Not enough information provided	Not enough information provided	Maternal: 17 Neonatal offspring: 13
[17] Fiala	NA	NA	NA
[4] Bogdanet	121	10	9
[11] Mehra	Not enough information provided	Not enough information provided	Not enough information provided
[13] Townsend	96 identified in SR, 56 included in the first round	7	11
[12] Perry	71	21	12
[9] Healy	103	Not enough information provided	22

GDM = Gestational diabetes mellitus; **IQR** = Interquartile range; **NA** = Not applicable; **SR** = Systematic Review



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The full report in Swedish

The full report "Core outcome sets inom förlossningsvård" (in Swedish), www.sbu.se/309

Appendices

1. Search strategies
2. Checklist modified after Core Outcome Set-STANDards for Reporting (COS-STAR)
3. Excluded articles
4. Ongoing studies

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