

Care bundles for women during pregnancy, labor/birth, and postpartum: a scoping review protocol

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ABSTRACT

Objective: This scoping review will identify the existence and type of care bundles developed, evaluated, or used by health care professionals in providing maternity care to women during pregnancy, labor/birth, and postpartum.

Introduction: Care bundles consist of at least 3 to 5 evidence-based health care interventions that are implemented together in 1 clinical episode, consistently. Care bundle use is predicated on the notion that better clinical outcomes can be achieved when the interventions, often existing as part of standard care, are used collectively rather than in isolation. Although widely adopted in some health care sectors (eg, in critical care), care bundle use during pregnancy, labor/birth, and postpartum appears relatively recent.

Inclusion criteria: This review will include records on women during pregnancy, labor/birth, and postpartum (up to 6 weeks) as recipients of care bundles applied by a health care professional. Women may be at low or high risk of maternity complications, receiving maternity care in hospital, community, or home settings, in any geographical location. Care bundles applicable to neonates will be excluded.

Methods: The Maternity and Infant Care, MEDLINE, CINAHL, Embase, and Epistemonikos databases will be searched from 2000 onward. The concepts of “care bundles” AND “maternity care” will underpin the search strings. Language limitations will not be applied, although only records published in English will be included. Two reviewers will independently assess the records for inclusion and extract the data. The findings will be charted using narrative summary text, illustrative tables, and illustrative figures.

Scoping review registration: Open Science Framework <https://osf.io/bdwfy/>

Keywords: care bundles; health care intervention; maternal health; maternity care; scoping review

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Introduction

National and international guidelines^{1,2} affirm that high-quality, woman-centered maternity care is a priority irrespective of the health care setting or geographical location. Maternity care, in its broadest form, encompasses care provided to women, babies, and their families during pregnancy, labor and birth, and in the postpartum period, generally up to 6 weeks following birth.³ The care provided during the maternity period is also broad, ranging from monitoring, assessing, and supporting the

physical health and well-being of women and their babies, to providing perinatal health information to women and families, or offering women emotional, psychological, and psychosocial support throughout the maternity continuum.³

Continuously developing, evaluating, and improving care practices is integral to the provision of safe maternity care. For example, early initiation of breastfeeding after birth (within 1 hour) is important for women as well as babies because breastfeeding helps contract the uterus, thereby reducing the risk of postpartum hemorrhage.⁴ However, rates of early initiation of breastfeeding in some countries are low.⁵ In India, a quality improvement initiative was conducted in 1 hospital by a team of maternity care providers, who analyzed the reasons for delayed

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initiation and then tested change ideas in practice. This initiative increased early initiation of breastfeeding from 12% to 80% within 3 months.⁴ Developing, evaluating, and assimilating evidence-based interventions into clinical care is also an important component of quality, safe maternity care. Interventions shown to reduce maternal mortality and morbidity are numerous, for example, audit and review of maternal deaths,⁶ prophylactic antibiotics for women undergoing cesarean birth,⁷ and calcium supplementation during pregnancy to reduce mortality and morbidity related to pre-eclampsia.⁸ Interventions are typically introduced into clinical practice singularly, that is, as a standalone intervention for the clinical condition for which they were designed. Increasingly, however, interventions that often exist as part of standard care are being considered for use collectively as a package. These packages, titled “care bundles,” have the potential to prevent, minimize, diagnose, or treat maternal adversity or ill health, including maternal mortality and severe morbidity.⁹

The concept of care bundles was introduced in 2001 by the Institute for Healthcare Improvement (IHI), a non-profit organization founded in 1991 in the United States as part of the National Demonstration Project in Quality Improvement in Healthcare. A care bundle is defined as “a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually.”^{10(p.2)} The “small set” that makes up a care bundle is generally assumed to be at least 3 to 5 interventions that already exist as part of standard care.¹¹ Care bundles are predicated on the premise that, although each discrete intervention in the bundle may be considered a single evidence-based intervention, when

combined together in a package of care that is “applied to an individual in one clinical episode”^{12(p.2)} by all health care providers, every time and in their entirety, both care quality and care outcomes will be improved.¹² The first care bundles to be implemented were the IHI ventilator bundle and the IHI central line bundle. These bundles are used in the intensive care unit to reduce ventilator-associated pneumonia (VAP) and central line infections, respectively.¹⁰ The elements that make up the bundles (Table 1¹¹) are applied consistently and collectively by all patient care providers when implementing the bundles. The decision to develop or use a care bundle may be driven at governmental level or through professional organizations (see Table 2 for examples). Alternatively, it may arise from clinical director and multi-disciplinary decision-making at local or regional levels.¹⁰

Care bundles are now commonly used for certain health conditions (eg, VAP, stroke care, surgical site infection) due to evidence of positive effects.¹³⁻¹⁵ For example, in Belgium, VAP care bundles reduced rates of VAP from 28% in 2010 to 11.3% in 2014.¹⁶ Similar effects have been noted with the surgical site infection care bundle. This bundle consists of interventions related to antibiotic selection, skin preparation, bowel preparation, hygiene, and antiseptic use, maintaining normothermia during surgery, and the use of clean instruments for closure. A reduced surgical site infection rate from 11% to 4.1% has been reported.¹⁵

However, the use of care bundles in maternity care appears relatively recent. Currently, the most widely known care bundle is the obstetric anal sphincter injuries care bundle. This bundle, which was developed between 2014 and 2016, is used during childbirth in caring for a woman’s perineum. The care bundle consists of 4 evidence-based

Table 1: Institute for Healthcare Improvement care bundles¹¹

IHI ventilator bundle	IHI central line bundle
1. Elevation of the head of the bed to between 30 and 45 degrees 2. Daily “sedation vacations” and assessment of readiness to extubate 3. Peptic ulcer disease prophylaxis 4. Deep venous thrombosis prophylaxis 5. Daily oral care with chlorhexidine (added in 2010)	1. Hand hygiene 2. Maximal barrier precautions 3. Chlorhexidine skin antisepsis 4. Optimal catheter site selection, with avoidance of using the femoral vein for central venous access in adult patients 5. Daily review of line necessity, with prompt removal of unnecessary lines

IHI, Institute for Healthcare Improvement.

interventions, namely, antenatal information, manual perineal protection, mediolateral episiotomy (if required), and diagnosing perineal tears.¹⁷ The care bundle has been evaluated in a stepped wedge cluster trial involving 16 maternity units in the United Kingdom, demonstrating a 20% reduction in the risk of obstetric anal sphincter injuries after the introduction of the bundle.¹⁸ Semi-structured interviews were also held with 19 women to determine their experiences of the bundle.¹⁹ Although compliance with the bundle was not measured, the women reported that the bundle did not intrude on their physical integrity. Further evaluation of the care bundle through an upscaled implementation-effectiveness project is planned.²⁰

Recognizing that maternity care involves caring not only for the woman, but also for her baby, this

scoping review focuses exclusively on care bundles for pregnant, labor/birthing, and postpartum women, and not for neonates. This is because following birth, the neonate has discrete care needs as a separate and distinct individual. This may include care in the neonatal intensive care unit, for which several care bundles have been developed and applied.^{21,22} Neonate bundles could be the focus of a separate scoping review. Nonetheless, care bundles for women who are pregnant or in labor may incorporate an element of caring for the fetus in utero even though, clinically, the care bundle is applied to the woman (eg, a fetal monitoring care bundle).²³ Table 2 presents examples of some maternity care bundle implementation and development projects.^{18-20,23-26}

An initial broad search of MEDLINE and Google Scholar using the terms “care bundle” AND

Table 2: Examples of care bundles

Name of care bundle and reference(s)	Clinical condition	Developers	Rationale for development	Type of record(s) reporting on the care bundle	Population
Maternal Safety Bundle for Obstetric Hemorrhage ²⁴	Peripartum hemorrhage	Multidisciplinary work groups of the National Partnership for Maternal Safety under the guidance of the Council on Patient Safety in Women's Health Care (USA)	To reduce rates of obstetric hemorrhage, which is a common, yet preventable complication of childbirth	Professional organization guideline; journal paper describing the intervention elements of the bundle	Women during pregnancy, labor/birth, and postpartum
Saving Babies Lives Care Bundle ²⁵	Stillbirth	Clinicians, commissioners, charities, and royal colleges (UK)	To reduce stillbirth as a mandate objective from the government to the National Health Service, England	Journal paper reporting a stepped-wedge trial implementation project	Women during pregnancy, labor, and birth
Safer Practice in Intrapartum Care ²³	Electronic fetal monitoring	The National Patient Safety Agency, the RCOG and the RCM, in collaboration with the Department of Health and Social services Public Safety (UK)	Developed as part of a pilot project to test the theory on care bundle use in maternity care	Government department report on a pilot project to evaluate the 6 components of suggested electronic fetal monitoring care bundle	Women during labor and birth
Obstetric and Anal Sphincter Injuries (OASI) Care Bundle ¹⁸⁻²⁰	Perineal care/perineal injury	Collaborative effort by the RCOG and the RCM; working groups established consisting of obstetricians, midwives, methodologists, and lay members from the Women's Network	In response to the rising rates of obstetric anal sphincter injuries (3-fold rise in England between 2000 and 2011)	Journal papers reporting the development, evaluation, and implementation of the care bundle	Women during birth
Postpartum Hemorrhage Care Bundles ²⁶	Postpartum hemorrhage	Twenty-three global maternal health experts (international)	To reduce postpartum hemorrhage, which occurs in approx. 5% of all births and is a leading cause of maternal death	Journal paper reporting the development of evidence-based bundles for care of postpartum hemorrhage	Women in the postnatal period

RCM, Royal College of Midwives; RCOG, Royal College of Obstetricians and Gynaecologists.

“maternity care” and a search of systematic review databases and registries revealed only 1 PROSPERO-registered project on care bundles in pregnancy (CRD42014010583). This protocol considers the use of bundles in midwifery care only, and is described as a rapid review of the literature.²⁷ The scope of this review is narrower and differs to our scoping review as the participants are midwives. Thus, to the best of our knowledge, no comprehensive scoping review on the use of care bundles in the broader context of maternity care has been undertaken. As this topic is relatively novel, a scoping review was considered the most appropriate approach because it will enable us to identify and describe the existence and types of care bundles that have been developed, evaluated, or implemented in maternity care. Depending on the type of evidence uncovered, this review may also determine the need for future systematic reviews on maternity care bundles.

The objectives of the scoping review are to:

- i) identify care bundles that have been developed, evaluated, or implemented for use by a health care professional for women during pregnancy, labor/birth, and up to 6 weeks postpartum;
- ii) describe the clinical conditions (eg, perineal care during childbirth,¹⁸⁻²⁰ postpartum hemorrhage²⁶) for which these care bundles are being applied;
- iii) describe the intervention elements of the identified care bundles (ie, the individual treatments or practices that constitute the bundle);
- iv) identify the type of evidence available (ie, study designs) for these care bundles to determine the need for future systematic reviews.

Review question

What care bundles have been developed, evaluated, or implemented for women during pregnancy, labor/birth, and postpartum, and for what conditions?

Inclusion criteria

Participants

This review will consider studies involving women during pregnancy, labor/birth, or postpartum (up to 6 weeks), of any age, level of schooling, or other demographic variable, or risk level for maternity complications, who are receiving maternity care from any health care professional (eg, obstetrician, family physician, midwife), irrespective of years of experience in their profession.

Concept

The concept of interest is studies or records that report on the development, evaluation, or implementation of a care bundle that health care professionals will use for women during pregnancy, labor/birth, or postpartum. A care bundle is defined as per the IHI definition of at least 3 (or more) evidence-informed practices delivered collectively and consistently by health care professionals to improve maternal health outcomes.¹⁰ Care bundles applicable to neonates will be excluded.

Context

The context is the provision of maternity care to women in hospital, community, or home settings in any geographical location. Maternity care is broadly defined to encompass the period from pregnancy (any gestation), labor and birth, through to 6 weeks postpartum, which is the standard follow-up time for postpartum maternal review. This means that the care bundle could be used by health care professionals for women as they access care in maternity hospitals, community birth settings (eg, standalone birthing units or community-based antenatal and postnatal clinics), or in the home.

Types of sources

All study designs will be considered for inclusion. Specifically, these will include randomized controlled trials (parallel and cluster), quasi-randomized and non-randomized clinical trials, prospective and retrospective cohort studies, controlled before-and-after studies, interrupted time-series studies, case-control studies, analytical or descriptive cross-sectional studies, development/validation studies, and systematic reviews. Qualitative studies of any design that report on women's views or experiences of a maternity care bundle during pregnancy, labor/birth, and postpartum, will also be considered for inclusion. Lastly, policy or practice guidelines, or text and opinion papers related to the use or implementation of a maternity care bundle will be considered for inclusion in the scoping review.

Methods

The proposed scoping review will be conducted in accordance with JBI methodological guidance for scoping reviews²⁸ and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

(PRISMA-ScR).²⁹ The scoping review title has been registered in the Open Science Framework repository (<https://osf.io/bdwfy/>).

Search strategy

The search strategy will aim to locate published, unpublished, in press, and ongoing studies, as well as policy or practice guidelines related to maternity care bundles as per our participants-concept-context criteria. The “care bundle” search string will be informed by a similar search string developed and used successfully in a recently published review, led by co-author VS, on care bundles for patients with COVID-19 in the intensive care unit.³⁰ The search string for this review was developed by an information retrieval specialist and subjected to peer review by a topic expert. To link the “care bundle” concept with the participant and context components of this scoping review, and to further optimize the relevancy of search terms, an initial broad search of MEDLINE (Ovid) was undertaken using the terms “care bundle” AND “maternity OR pregnancy.” The text words contained in the titles and abstracts of the 345 records retrieved in this broad search, and the index terms used to describe the records, were then used to develop the search strategy for this scoping review (Appendix I). The search strategy was collectively developed and agreed on by the review authors and peer-reviewed independently by the university subject librarian.

The following electronic databases will be searched for eligible records: Maternity and Infant Care (MIDIRS), MEDLINE (Ovid), CINAHL (EBSCOhost), Embase (EBSCOhost), and Epistemonikos (for systematic reviews). The search strategy will be applied similarly to all databases, with database-controlled vocabulary adaptations as relevant for index and subject heading terms. As the concept of care bundles was introduced in 2001, we will search each database from the year 2000 to the date of our search, and will determine that the care bundle referred to in the retrieved records meets the IHI definition of a care bundle.

The electronic database search will be supplemented by a comprehensive search for additional gray literature. The established gray literature databases OpenGrey System for Information on Grey Literature in Europe, the Open University dedicated gray literature site, the World Health Organization’s International Clinical Trials Registry Platform, and

the LENUS repository will be searched. The following professional body websites will also be searched for potential guidelines, policies, or information on the use of care bundles in maternity care: Irish Society of Obstetric Anaesthesia, Royal College of Obstetricians and Gynaecologists, American College of Obstetricians and Gynecologists, Society of Obstetricians and Gynaecologists of Canada, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, European Board and College of Obstetrics and Gynaecology, and the Royal College of Midwives. Lastly, the reference lists of all records identified as eligible for inclusion in the scoping review will be screened for potentially relevant additional studies not already captured in our search.

Language limitations will not be applied to the search strategy; however, only records published in English will be included. By searching all languages, we will identify non-English records that may potentially meet the review’s inclusion criteria and note these, as appropriate, as a possible source of language bias.

Study selection

Following the search, all identified citations will be collated and uploaded into EndNote v20 (Clarivate Analytics, PA, USA) and duplicates removed. The remaining citations will be uploaded into Covidence (Veritas Health Innovation, Melbourne, Australia). An initial pilot test will be conducted, whereby the titles and abstracts of the first 10 records will be screened by 2 reviewers independently against the inclusion criteria. These will be compared to ensure congruency in the interpretation of our eligibility criteria. Following this, all retrieved records will be screened by title and abstract by 2 reviewers independently. Records assessed as potentially eligible, or those whose relevance is uncertain, will be retained for full-text review. The full text of selected citations will be assessed in detail against the inclusion criteria by 2 reviewers independently. Reasons for excluding records at full-text screening will be documented and reported. Any disagreements that arise between the reviewers at each stage of the selection process will be resolved through discussion or with a third reviewer. The results of the search and the record selection process will be reported in detail in the final scoping review and presented in a PRISMA flow diagram.³¹

Data extraction

Data will be extracted from included papers by 2 reviewers independently using a data extraction tool developed by the reviewers for the purposes of this scoping review. The data extraction tool will be based on the JBI data extraction template and adapted accordingly (Appendix II).²⁸ Current adaptations include adding a row for “type of evidence source” and rows to extract specific details to address the objectives of the review. The form will be piloted on 2 included records by 2 reviewers independently to ensure that it adequately meets the purpose of the review. Any refinements following the pilot test will be described in the scoping review.

Data to be extracted will include specific details about the participants, such as age and stage in the maternity continuum (antenatal, labor/birth, or postpartum); details on the health care professional using the bundle (where reported); the care bundle concept, including conditions for which the care bundles are being developed, evaluated, or used; and details on the intervention elements of the bundle. Details on the maternity care context will also be extracted as well as study methods, including study design and any additional key findings (eg, list of outcomes measured in effectiveness studies, rates of compliance and fidelity to the bundle, list of themes reflecting women’s views and experiences of bundle use) relevant to the objectives of this scoping review. As this scoping review will describe the existence and type of care bundles being used in maternity care, a quality appraisal of the included records is not required.

Data analysis and presentation

Data analysis will involve narrative summaries, illustrative tables, and illustrative figures. Descriptions of the included records will be narratively summarized based on record or study characteristics, that is, type of record (eg, study, policy, guideline), year published, aim of study, clinical condition for which the care bundle was designed or applied, and types of interventions included in the bundle.

This narrative summary will be supplemented by a table with the characteristics of included studies. A bubble chart will be used to map and present the trajectory of care bundle development, evaluation, or implementation by year, that is, the number of care bundles developed, evaluated, or implemented in any given year. A color-coded bar chart will be

used to map the study design or source type reporting on the care bundle to present source numbers and any differences in these. Thus, a bar will represent the numbers of records by the type of record reporting on a care bundle (eg, randomized trial, qualitative study, clinical guideline), and these bars will be differentiated by color. The components of the care bundles will be mapped to the clinical conditions in tabular format to illustrate any overlap of components across bundles. Lastly, for any studies reporting on the clinical effectiveness of a care bundle, the outcomes measured in these studies will be tabulated. Similarly, for any studies reporting on women’s views and experiences of a care bundle, we will tabulate a list of the key themes. Charting the types of studies and the outcomes/themes reported in them will also help determine the need for a future quantitative or qualitative systematic review.

Acknowledgments

J. Vendt, a Cochrane information specialist, who developed the care bundle search string for a previous systematic review on care bundles for patients with COVID-19 in the intensive care unit, which comprises part of the search strategy in this scoping review.

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Author contributions

VS conceived the idea for the scoping review. TR and VS collectively developed and agreed the review’s inclusion criteria, search strategy, and methods. TR and VS read and approved the final version of the manuscript prior to submission for potential publication.

Declarations

VS is an experienced systematic reviewer and a senior Cochrane Ireland systematic review trainer. VS recently led a rapid scoping review commissioned by the World Health Organization (WHO) on care

bundles for use in patients with COVID-19 and related conditions in the intensive care unit. The findings of the review directly informed the WHO's interim clinical care guidelines for COVID-19.

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Appendix I: Search strategy

For application and adaptation (as required) across all databases

Participants

(MeSH): Pregnancy OR Obstetrics OR Maternal-Child care OR childbirth OR prenatal care OR perinatal care OR postnatal care OR

(Keywords): (pregnan* OR birth OR intrapart* OR antenatal OR prenatal OR antepartum OR perinatal OR puerperal OR puerperium OR postnatal OR postpartum OR peripartum OR post-natal OR post-partum OR ante-natal OR ante-partum OR pre-natal OR peri-natal OR obstetric*) *ti,ab*

AND

Concept

(MeSH): Care Bundle OR Clinical Protocol OR

(Keywords): bundl* OR “consensus bundle” OR “care protocol” OR “care package” OR “care algorithm” OR “care protocols” OR “care packages” OR “care algorithms” OR “treatment protocol” OR “treatment package” OR “treatment algorithm” OR “treatment protocols” OR “treatment packages” OR “treatment algorithms” OR “clinical protocol” OR “clinical package” OR “clinical algorithm” OR “clinical protocols” OR “clinical packages” OR “clinical algorithms” *af*

[*ti,ab* = title and abstract; *af* = all fields]

MEDLINE (Ovid)

1 November 2000–22 July 2022

#	Term	Results
1	Pregnancy.sh	958,239
2	Obstetric.sh	24,152
3	Perinatal care.sh	5223
4	Postnatal care.sh	6290
5	(pregnan* OR birth OR intrapart* OR antenatal OR prenatal OR antepartum OR ante-natal OR ante-partum OR pre-natal perinatal OR puerperal OR puerperium OR peri-natal OR postnatal OR postpartum OR peripartum OR post-natal OR post-partum OR obstetric*).ti.ab.kw	1,042,126
6	1 OR 2 OR 3 OR 4 OR 5	1,414,239
7	Clinical Protocols.sh	29,744
8	(bundl* OR consensus bundle OR care protocol OR care package OR care algorithm OR care protocols OR care packages OR care algorithms OR treatment protocol OR treatment package OR treatment algorithm OR treatment protocols OR treatment packages OR treatment algorithms OR clinical protocol OR clinical package OR clinical algorithm OR clinical protocols OR clinical packages OR clinical algorithms).af.kw	2142
9	7 OR 8	31,806
10	6 AND 9	1879
11	Limit 10 to years="2000 to current"	1248

ab=abstract; af=all fields; kw=keyword; sh=medical subject heading; ti=title

Appendix II: Draft data extraction instrument

Scoping review details	
Person extracting the data:	
Date data extracted:	
Scoping review title:	
Review objectives:	
Inclusion/exclusion criteria	
Population	
Concept	
Context	
Types of evidence source	
Evidence source details and characteristics	
Type of evidence source	
Citation details (eg, author/s, date, title, journal, volume, issue, pages)	
Country of origin	
Description of maternity setting	
Details/results extracted from source of evidence (in relation to the concept of the scoping review)	
Year the care bundle was developed and by whom	
Status (in development, piloting phase, implemented)	
Description of participants (women as recipients of the care bundle)	
Description of care bundle (clinical condition, pregnancy stage [ie, antenatal, intrapartum, postpartum, or all 3]), health care professional using the bundle)	
Details of the components of the care bundle	
Outcomes measured (if relevant) and listed themes (for qualitative studies, if relevant)	