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Influences on patient safety in intrapartum electronic fetal heart rate monitoring with cardiotocography (iSafe): protocol for a systematic scoping review

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Amendments

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1 Introduction

1.1 Background

Intrapartum electronic fetal monitoring (EFM) using cardiotocography (CTG) is the recommended method for monitoring the fetal heart rate during labour for high-risk births in England.[1] An abnormal CTG indicates the need for further review and management including potential urgent intervention (e.g. expediting birth) to minimise risk of serious long-term harm to the baby or stillbirth. In the UK, as other European countries, sub-optimal intrapartum EFM management is implicated in a large share of cerebral palsy, birth asphyxia, peripartum hypoxic brain injuries and obstetric malpractice claims.[2-5] In addition to the psychosocial and social impact of stillbirth or life-long disability on parents and babies, obstetric brain injury is costly, [6] potentially resulting in settlements for millions of pounds to support families over a lifetime of care. Every baby born in the NHS in England now incurs indemnity costs of £1,100. Of the total Clinical Negligence Scheme for Trusts provision of £78bn, 70% relates to maternity. [7] Though maternity claims made up just 10% of the number of clinical negligence claims received by NHS Resolution in 2018-19, they accounted for 50% of the total value of claims. [7] The need for action to improve safety of intrapartum EFM is now urgent, but questions remain about how it can best be achieved.

We propose that reducing avoidable harm linked to intrapartum EFM requires sound understanding of the influences on sub-optimal practice. However, current approaches to improvement have tended to focus overwhelmingly on one element of the system – interpretation of CTG traces – and have also tended to focus on one type of solution – specifically training. There can be no doubt of the relevance of CTG interpretation to quality of care. High rates of inter- and intra-observer variability in interpretation of CTG traces are often reported. [8 9] However, the evidence that CTG interpretation training on its own is effective is weak. As early as 2007, 98% of UK maternity units declared that they complied with the requirement that six-monthly training sessions on high-risk labour and CTGs be attended by all clinicians.[10] But reports continue to attribute cases of cerebral palsy and stillbirths to poor CTG interpretation and failure to act on abnormal CTGs,[2 6] suggesting that just training staff in CTG interpretation alone is not enough to improve quality of care in relation to intrapartum EFM.

In addition, technology does not appear to be the answer to the interpretation challenge, at least at present: a recent (2017) large randomised controlled trial of a computerised decision support system for electronic fetal monitoring did not indicate any benefit to clinical outcomes.[11] One explanation is that responses for abnormal intrapartum CTG traces were variable, indicating a potential systems issue going beyond the specifics of interpretation.[12]

In recent years, efforts have been made to acknowledge the wider context of EFM beyond interpretation. The 2015 RCOG report recommended that EFM training should promote team-working and include non-clinical skills such as situational awareness.[13] The 2019 NHS Saving Babies' Lives Care Bundle 2 specifies that EFM training must include situational awareness and human factors, [14] although there is currently no standardised curriculum which outlines the nature of such training, and local training approaches are variable.

A perhaps more fruitful approach than one that focuses solely on CTG interpretation, more technology and/or solely on training, is to look more broadly at influences on safety. [15] Such an approach would be consistent with the literature in patient safety that has advocated a systems approach to understanding and addressing the effects and interactions of real-world contexts such as teamwork, tasks, equipment, workspace, culture and organisation on clinical performance. [16 17] It is also consistent with a well-established definition of safety as an attribute of health systems:

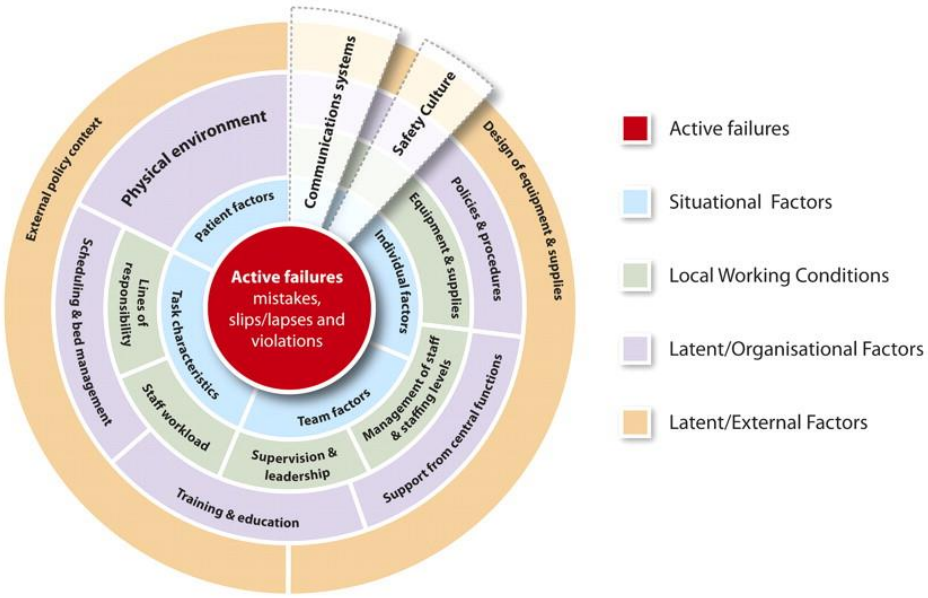
> *Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.* [18]

Many relevant influences on patient safety have been summarised in the Yorkshire Contributory Factors framework (the Framework) (Figure 1), an evidence-based conceptual framework of 20 domains (and a definition for each) that may contribute to patient safety incidents in hospitals. [15] It is based on a synthesis of 95 reports of 83 studies conducted in multiple healthcare settings, including general hospital (30), intensive care (17), surgery (16), and anaesthesia (7). The 20 domains generated from the studies reviewed by the authors range from the situational (e.g. individual or team factors) to the external, such as national policies.

A particularly welcome feature of the Framework is that it seeks to avoid excessive focus on proximal causes of incidents (active failures) and instead broadens to a more systems-based approach that considers how working conditions and latent factors may be highly consequential. Across the study settings reviewed by the authors of the Framework, the five contributory factors identified most frequently in the 95 studies reviewed by the authors were active failures (slips, lapses, mistakes, deviations from policy) (18.2%), individual factors (11%), communication (7.9%), equipment and supplies (6.6%) and management of staff and staffing levels (5.8%). Active failures and individual factors were the most frequently identified contributory factors, but team factors (8.5%) were reported among the top five contributory factors for surgery and for no other setting, while in anaesthesia, equipment and supplies was the second most cited contributory factor, accounting for 15.2%. Physical environment was also among the top five factors. For the general hospital setting, patient factors (7.4%) were among the highest ranked contributory factors but equipment and supplies were not.

An approach that draws on this kind of framework is likely to be of considerable value in characterising the influences on intrapartum EFM safety in maternity units, where issues such as work organisation, availability of senior support, and professional boundaries are known to play a role. [6 19-21] However, the evidence about what is known regarding the specific influences on EFM and labour management has not been systematically collated nor organised into this kind of explanatory framework. This absence limits the development of a fully characterised systems approach to the area and inhibits recognition of which issues have received most and least attention in building the evidence base. Addressing this void is the goal of our proposed review, with the aim of identifying new areas for intervention and determining what kinds of training, interventions and service delivery and organisation are required to improve maternal and fetal outcomes.

Figure 1: The Yorkshire Contributory Factors framework



Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

(reproduced from Lawton et al, 2012 [15])

2 Review question and objectives

We will conduct a scoping review of the literature to answer the following question:

- What are the influences on patient safety of intrapartum electronic fetal monitoring (EFM) with cardiotocography (CTG) in hospital-based maternity care settings?

Our primary objective is to provide an overview of the available evidence that can help in identifying and characterising the range of influences on safety of EFM, using an end-to-end systems approach, including but not limited to interpretation, response, and management of CTG traces. A secondary objective is to identify which influences feature most strongly in the literature so that that an assessment can be made of which topics have thus far received most research attention, and which might benefit from further study.

The review does not aim to examine the effectiveness of CTG training, which is the subject of a separate systematic review (Health professional training for cardiotocography interpretation and management; PROSPERO reference CRD42018082567).

3 Methods and analysis

We will use a scoping review approach, because of the particular value of this method when there is a need to explore concepts, map the nature and type of available evidence for a question, or conduct a first comprehensive review of a body of literature. [22 23] Scoping reviews 'follow a systematic approach to map evidence on a topic and identify main concepts, theories, sources, and knowledge gaps', [22] and can be contrasted with systematic reviews, which seek to address a clearly defined question. Scoping reviews do not aim to examine the effectiveness of interventions.

Our review will combine scoping methodology with a best-fit framework synthesis approach, [24 25] using the domains of the Framework to organise the initial analysis.

3.1 Conduct and reporting

Methods for the conduct and reporting of the systematic scoping review will follow the guidelines of the PRISMA-ScR statement. [22] There is currently no specific guidance for reporting a protocol for a systematic scoping review, so this protocol has been developed based on key elements of the PRISMA-P guidance, [26] earlier scoping review frameworks [23 27] and the PRISMA-ScR statement. [22]

PROSPERO [28] does not currently accept registrations for scoping reviews so this protocol is being made publicly available on the THIS Institute website (https://www.thisinstitute.cam.ac.uk/) and institutional repositories.

3.2 Eligibility criteria

Given the wide scope of the review and the literature, the inclusion/exclusion criteria and search strategies have been developed through initial exploratory searches, piloting of title and abstract screening and an iterative learning process and discussion about areas of uncertainty in collaboration between THIS Institute and RAND Europe.

3.2.1 Types of studies

We will include empirical studies (primary empirical research or secondary data analysis of primary empirical data) that report data concerning influences on the clinical practice of intrapartum electronic fetal heart rate monitoring with cardiotocography in hospital-based maternity care settings.

Study designs will not be restricted: we will include interventional and observational quantitative designs (i.e. randomised controlled trials, controlled trials, before-and-after intervention study designs, cohort studies, cross-sectional studies), qualitative studies, case reports and case studies. We will include research articles from peer-reviewed journals and conference proceedings and relevant grey literature reports, published in English

Editorial material, letters and literature reviews (literature reviews, systematic reviews, meta analyses) will be excluded. Reference lists of any relevant reviews identified will be hand-searched. We note that some relevant journals, such as ANZJOG, do not have a traditional abstract written by the authors, but instead provide an editorial comment: despite this, these studies are regular peer-reviewed articles, and they will not be excluded at initial screening unless they clearly meet exclusion criteria.

Studies from lower or middle income (LMIC) countries (as defined by the World Bank [29]) will be excluded as LMIC countries may be less likely to use EFM or have less capacity to take action if abnormalities are identified).

3.2.2 Date of publication

Studies published from 2001 onwards will be included. UK and US national guidelines on EFM were introduced after this date; findings from before 2001 are less likely to be relevant to current practice.

3.2.3 Population

We will include studies relevant to intrapartum EFM and CTG interpretation in hospital-based maternity care including (but not limited to) the roles of obstetricians, midwives and other members of the maternity team, wider organisational and environmental influences and maternal and fetal experience.

3.2.4 Focus of studies

The primary focus for inclusion is studies that report influences on maternal and/or fetal safety in relation to EFM. In keeping with the Framework and the systems approach to patient safety, we will not limit our analysis to proximal influences on safety. For example, some studies have analysed the impact of architecture on coordination, communication and situational awareness in maternity units in general [30] which in turn may affect EFM. These studies will be included.

3.2.5 Phenomena of interest

Phenomena of interest are (i) findings relating to safety of EFM as described in the domains of the Framework (ii) any further relevant influences identified by our review that do not fit in these domains.

3.2.6 Setting

We will only include studies in hospital intrapartum maternity care settings (i.e. delivery suites/labour wards).

3.2.7 Exclusion criteria

- Studies that relate to EFM but do not report on patient safety.
- Fetal heart rate monitoring using non-electronic methods (such as intermittent auscultation); studies reporting about the partogram unless EFM is also reported.
- Studies focusing on: pre-birth (ante-natal) monitoring only; non-stress tests (NST), contraction stress tests (CST) and oxytocin challenge tests (OCT) as they are performed before labour, as part of antepartum surveillance.
- Studies that focus on a link between a specific clinical intervention (e.g. caesarean section) and a clinical outcome (e.g. cerebral palsy), without a plausible link to factors related to EFM performance.
- Studies that report the prediction/diagnostic relationship between CTG traces and fetal outcomes.
- Studies that report patient safety incidents without an examination of the factors that contributed to incidents.
- The review does not aim to consider the effectiveness of interventions targeted at staff training or education about CTG (as this is the subject of an ongoing systematic review as described previously). However, contextual issues around these topics such as lack of training influencing CTG interpretation and response, or factors that may affect uptake or participation in education or training will be included.
- The review does not aim to consider the effectiveness of new or different technologies for EFM such as technical algorithms, waveform analyses, technical add-ons to CTG, computerised interpretation.
- Studies not published in English.
- Studies conducted in lower or middle income (LMIC) countries.

3.3 Information sources and search strategy

3.3.1 Databases

A number of approaches will be taken to identify relevant literature.

The following electronic sources will be searched for peer-reviewed studies and conference abstracts published in the English language: MEDLINE; EMBASE; CINAHL; Web of Science; Scopus, British Nursing Database (formerly British Nursing Index), Cochrane library. Combining MEDLINE and CINAHL is recommended when searching for qualitative research.[31] The Web of Science Core Collection and Scopus will be included because they cover a

broader disciplinary range, including social sciences, management, and engineering, which may include useful references.

A draft database search strategy for MEDLINE is shown in Appendix 1. This search strategy was developed with the involvement of an experienced medical librarian and information specialist (IK), following initial exploratory searching and scoping and analysis of search hits. The categories of the Framework and advice on relevant search terms from an obstetrician (TD) and a midwife (CW) with professional experience of intrapartum EFM/CTG were also used to inform the searches. The search strategy will be translated as appropriate for the other electronic databases.

The search strategy developed combines keywords and MeSH terms (1) related to safety concerns in medical and maternity care and to good and poor practice, maternal and fetal outcomes and other issues related to maternity care, and (2) related to the use of EFM/CTG in labour, e.g. fetal heart rate monitoring or cardiotocogram.

Additional targeted searches, hand searching and forward and backward citation searching will also be conducted as appropriate using a flexible, iterative approach consistent with scoping review methodology to identify any further potentially relevant studies.

3.3.2 Grey literature

We will also conduct a targeted search of the grey literature. We will search websites of national professional bodies relating to obstetrics, midwifery and patient safety to identify key reports from public authorities and national professional bodies (e.g. NICE; Royal College of Obstetricians and Gynaecologists; Royal College of Midwives; NHS Resolution; FIGO), that specifically relate to EFM recommendations and practice. Further grey literature searches will be conducted in NICE Evidence, OpenGrey and OpenSIGLE. Additionally, we will conduct complementary searches of Google Scholar using the same search terms and concepts as the database searches.

3.4 Selection of evidence

Search hits will be downloaded and screened using reference management software and/or other screening software/interfaces. Title and abstract screening will be conducted independently by at least two reviewers. Disagreements between the two reviewers will be resolved by discussion and with the involvement of a third reviewer if necessary. Full texts of potentially relevant papers will be obtained and screened independently by two researchers. In case of disagreement a third reviewer will arbitrate the final decision. The same screening criteria will be applied at both the title and abstract and full text screening stages. A PRISMA flow chart [32] will be used to document the study selection process.

3.5 Data extraction and data charting

For each paper included in the review, data will be extracted relating to study characteristics and key demographics. A standard template will be developed and piloted by the team before use. Data will be presented in the form of summary tables and/or diagrams for:

(1) study characteristics (study reference, year, country of origin, study design and type of evidence in relation to the factors reported (e.g. quantitative, qualitative, experimental, observational, case studies));
(2) key demographics where relevant e.g. for patients/participants (such as age, gender, health status, socioeconomic status, ethnicity);
(3) Any other contextual information of relevance;

This data extraction will be conducted by an experienced reviewer and cross-referenced with a second reviewer, with disagreements resolved by discussion. A formal quality assessment will not be conducted as this is not usually included within a scoping review. [22] However, as described above, the data tabulation process will report the sources and type of evidence. Further data extraction, relating to key findings of included studies, will be undertaken alongside data synthesis, as is typical in a best-fit framework synthesis approach: details of this are given below.

3.6 Synthesis of results

The review will seek to map relevant findings from the included studies onto the Framework [15] guided by a best-fit framework synthesis approach. [24 25] A coding framework will initially be created based on the 20 domains of the Framework. Relevant evidence to address the research question will be identified in the included studies and will be coded appropriately, facilitated by NVivo and/or Excel software. Some findings may fit into more than one domain, and multiple coding will be used as required. Where several papers report similar findings, these may be grouped together thematically where appropriate. “Memos” akin to those used in qualitative analysis will be used to capture coding decisions, facilitate analytic depth, and ensure sensitisation to emerging constructs.

Where evidence does not satisfactorily fit the domains of the existing Framework, thematic analysis of relevant findings will be used to generate new domains to add to the coding framework. Such domains will be created in discussion with the review team, and the developing coding framework will be reviewed regularly to ensure continuing relevance to the research question concerning influences on safety of intrapartum electronic fetal monitoring (EFM) with cardiotocography (CTG).

Initial coding and mapping will be conducted by an experienced reviewer and cross-referenced with a second reviewer. Disagreements between reviewers will be resolved by discussion or by arbitration with a third experienced reviewer. Regular project team meetings will facilitate close scrutiny of coding decisions and the emerging framework.

The Yorkshire Contributory Factors Framework is well-suited to the aims of this review: it was developed from identified patient safety incidents, it is relevant to studies in a hospital setting, and it provides categories/domains which are generic across a range of different types of treatment and care, including those relating to: failures in performance or behaviour; communication systems; design of equipment and supplies; external policy context; individual factors; lines of responsibility; management of staff and staffing levels; patient factors; physical environment; policy and procedures; safety culture; scheduling and bed management; staff

workload; supervision and leadership; support from central functions; task characteristics; team factors; training and education. The mapping will, in keeping with the Framework, distinguish between active failures, situational factors, local working conditions, latent-organisational factors, and latent external factors.

Use of the Framework will help in systematically identifying and characterising a wide range of influences on safety related to intrapartum EFM and CTG as reported in the literature, and will also help to identify which influences have received most attention to date in the research literature.

Note: additional members of the project team who may assist with selection of evidence, data extraction, data synthesis and charting are listed in Appendix 2.

4 Involvement of healthcare professionals (knowledge users)

This protocol has been developed with the involvement of experienced obstetricians and midwives with professional experience of using, and developing training for, intrapartum EFM and CTG interpretation (TD, CW). These professionals have advised on terms for the draft search strategy, and provided feedback on the protocol. They will also advise and feedback on the synthesis, discussion and conclusions of the full review.

5 Other stakeholders

RAND Europe as a partner of THIS Institute have been involved in development and piloting of the search strategy and inclusion/exclusion criteria for this protocol and will participate in the screening process.

6 Ethical approval

As this review will use published literature in the public domain, ethical approval is not needed.

7 Dissemination

A full report of the methods and results of the scoping review will be published as a paper in a high quality, peer-reviewed journal. Further dissemination will be conducted through social media, the website of THIS institute and the networks and contacts of THIS Institute. In addition, it is hoped that this report will help to inform future guidance and practice for clinical staff via their national professional bodies.

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10 Appendices

Appendix 1: Draft search strategy (MEDLINE)

Medline
Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to October 22, 2018>

Search Strategy:

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1 exp malpractice/ or exp "Drug-Related Side Effects and Adverse Reactions"/ or exp jurisprudence/ or exp legal cases/ or exp medical error/ or exp diagnostic error/ or exp accidents/ or exp risk/ or exp protective factors/ or exp "Compensation and Redress"/ or exp "quality of health care"/ or exp maternal mortality/ or exp infant mortality/ or exp fetal death/ or exp hospital mortality/ or exp morality/ or exp perinatal mortality/ or (Adverse or negligen* or medicolegal or medico-legal* or legal or illegal* or liabil* or safe* or claim* or litigat* or malpractice or error* or risk* or prevent* or fail* or accident* or incident* or mistak* or compensat* or ((good or bad* or poor* or best) adj3 (practic* or perform*)) or interpret* or misinterpret* or substandard* or quality or standard* or mortality or death*).mp.
2 (exp hypothermia, induced/ or ((induc* or therap*) adj3 (cool* or hypotherm*)).mp.) and (exp infant, newborn/ or (neonat* or infant* or newborn*).mp.)
3 (exp stillbirth/ or (stillbirth* or stillborn or (still adj (born* or birth*))).mp.)
4 (Exp infantile spasms/ or ((exp seizures/ or exp epilepsy/ or (seizure* or fit or fitting or fits or epilep*).mp.) and (exp infant, newborn/ or (neonat* or infant* or newborn*).mp.))
5 (exp brain diseases/ or (encephalo* or ((diseas* or disorder*) and (brain* or intracranial*))).mp.) and (exp infant, newborn/ or (neonat* or infant* or newborn*).mp.)
6 (exp apgar score/ or apgar.mp.)
7 (exp umbilical cord/ or (umbilical).mp.) and (exp delivery, obstetric/ or (intrapartum or birth* or delivery).mp.) and (exp acidosis/ or (acidosis or acidity or ph).mp.)
8 (((exp patient admission/ or exp patient transfer/) and (unexpect*).mp.) or (unexpect* adj3 (admission* or admit* or transfer*)).mp.) AND (exp intensive care, neonatal/ or exp intensive care units, neonatal/ or (nicu or (neonatal adj (critical or intensive) adj care)).mp.)
9 exp Cerebral palsy/ or exp asphyxia neonatorum/ or exp hypoxia-ischemia, brain/ or exp fetal hypoxia/ or exp hypoxia-ischemia, brain/ or exp pregnancy outcome/ or exp obstetric labor complications/ or exp pregnancy complications/ or cerebral palsy.mp. or (asphyx* adj3 (neonat* or birth* or intrapartum* or f?etus*)).mp. or hypoxi*.mp. or (complicat* adj3 (pregnan* or labo?r* or birth* or deliver*)).mp.

10 exp ABRUPTIO PLACENTAE/ or exp uterine rupture/ or (Abruptio* or pr?evia).mp. or ((ruptur* or tear* or separat* or torn* or solutio) adj3 (placent* or uteru* or uterine*)).mp.
11 or/1-10
12 exp Cardiotocography/ or exp fetal monitoring/ or ((f?etal or intrapartum*) adj2 (monitor* or heartbeat* or (heart adj2 (beat* or rate)) or distress* or surveillanc* or status)).mp. or (ctg or cardiotoco*).mp. or ("continuous electronic monitoring" adj3 (labo?r or delivery or intrapartum* or birth*)).mp. or ((f?etal or intrapartum) adj5 (decelerat* or accelerat* or variab*)).mp. or ((late or early) adj3 decelerat*).mp.
13 11 and 12

Appendix 2: Additional team members

Additional team members who may assist with review tasks such as selection of evidence, data extraction, data synthesis and charting: Xueying Nancy Zheng, Harry Kyriacou, Alice Egerton, Zi Qi Kok and Kathryn Jones.