Why is safety in intrapartum electronic fetal monitoring so hard? A qualitative study combining human factors/ergonomics and social science analysis

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Abstract

Background Problems in intrapartum electronic fetal monitoring with cardiotocography (CTG) remain a major area of preventable harm. Poor understanding of the influences on safety may have hindered improvement. Taking an interdisciplinary perspective, we sought to characterise the everyday practice of CTG monitoring and the work systems within it takes place, with the goal of identifying potential sources of risk.

Methods Human factors/ergonomics (HF/E) experts and social scientists conducted 325 hours of observations and 23 interviews in three maternity units in the UK, focusing on how CTG tasks were undertaken, the influences on this work, and the cultural and organisational features of work settings. HF/E analysis was based on the SEIPS 2.0 model. Social science analysis was based on the constant comparative method.

Results CTG monitoring can be understood as a complex sociotechnical activity, with tasks, people, tools and technology, organisational and external factors all combining to affect safety. Fetal heart patterns need to be recorded and interpreted correctly. Systems are also required for seeking the opinions of others, determining whether the situation warrants concern, escalating concerns, and mobilising response. These processes may be inadequately designed or function sub-optimally, and may be further complicated by staffing issues, equipment and ergonomics issues and competing and frequently changing clinical guidelines.

Practice may also be affected by variable standards and workflows, variations in clinical competence, teamwork and situation awareness, and the ability to communicate concerns freely.

Conclusions CTG monitoring is an inherently collective and sociotechnical practice. Improving it will require accounting for complex system interdependencies, rather than focusing solely on discrete factors such as individual technical proficiency in interpreting traces.

Key messages

What is already known on this topic

- Intrapartum electronic fetal monitoring has been repeatedly identified as a major area of preventable harm in maternity care
- Improvement efforts have typically focused on training targeting individuals' proficiency in cardiotocography trace interpretation, but have had limited impact in improving care overall

What this study adds

- Intrapartum electronic fetal monitoring should be considered as a practice fraught with sociotechnical complexity, where people, tasks, tools and technology, organisation, and environment interact to affect outcomes
- Many fetal monitoring work systems are sub-optimally designed and do not work well in practice, with substantial gaps between work as imagined and work as done

How this study might affect research, practice or policy

- Updated guidelines or more training are unlikely, on their own, to improve electronic fetal monitoring. Improvement initiatives need to consider a broader set of factors and their interdependencies to create the conditions for better CTG monitoring.
- Some issues may be amenable to local action, but others will require large-scale coordination.

Introduction

Problems with intrapartum electronic fetal monitoring (EFM) during labour have repeatedly been identified as a major area of preventable harm. [1] [2] [3] However, it has been remarkably difficult to secure improvement. [4] [5] One explanation for the limited progress lies in the possibility that improvement efforts may have been misdirected, typically focused primarily on individual behaviours in relation to cardiotocography interpretation[6] rather than the wider range of influences on risks, including systems, processes, decisions and actions. Examination of the everyday work of EFM is essential to understanding system factors and to identifying potential targets for intervention for improvement. To address this need, we undertook an interdisciplinary study drawing on both human factors/ergonomics (HF/E) and social science perspectives to examine the routine operation of local systems where EFM takes place.[7]

Increasingly widely promoted, [8] [9] the discipline of HF/E is characterised by a focus on the components of work systems and their interactions.[10] One of its key commitments is to understanding how tasks are conducted in practice (work “as done”), rather than how they are documented or prescribed (work “as imagined”).[11-14] The Systems Engineering Initiative for Patient Safety (SEIPS, Box 1) is an important example of an HF/E model that has been developed specifically for healthcare settings. Analysis using the SEIPS is intended to identify the range of influences on how work is done, and thus help in guiding system redesign to support better performance and safety.

A second important and complementary methodological approach to understanding the systems where work takes place involves the social sciences, including studies using qualitative methods such as ethnographic observations and interviews. Work in this tradition has been especially important in affording deep insight into cultural and organisational features of work settings, [15] [16] the role of technologies, [16, 17] [18] and influences on professional work and practices. [19] [20]

In this article, we combine these approaches –HF/E and social science – to characterise current work systems for electronic fetal monitoring in hospital maternity units with the aim of understanding influences on risk.

Box 1. Description of the SEIPS model

The Systems Engineering Initiative for Patient Safety (SEIPS)[21] takes a whole-system view that identifies the elements of systems using a structured framework and examines how they interact[22] to influence processes and, ultimately, outcomes. In version 2.0,[22] SEIPS contains three types of elements:

- The *work system* is composed of interacting components: persons (e.g., care providers or patients), tasks, tools and technology (e.g., medical devices or IT systems), organization, and internal environment (i.e. architectural layout and ambient characteristics, such as noise and light). The work system is affected by influences from the external environment.
- Components of the work system interact to produce *processes* of professional, patient, and collaborative work, at various levels: physical, cognitive, and social/behavioural.
- These processes affect the *outcomes* for patients, healthcare workers and organizations. These outcomes can be desirable or not, and close or distant in time.

This model integrates well-established work systems modelling principles with Donabedian's [23] classic structure-process-outcome framework for healthcare quality. Importantly, the work system and the processes are affected by previous outcomes through feedback loops, by which individuals and organizations adjust over time to maintain or improve performance.

Methods

This article is an output of the IMMO programme (IMproving the practice of intrapartum electronic fetal heart rate MOnitoring with cardiotocography for safer childbirth) [24] and its reporting is guided by the Standards for Reporting Qualitative Research.[25] We conducted a study combining observations and interviews in three maternity units, selected purposively based on their size (annual number of deliveries) and their location in different nations of the UK. We recruited one small unit (less than 2,000 births/year), one medium unit (2,000 to 5,000 births/year), and one large unit (more than 5,000 births/year), across rural, urban, and metropolitan settings. Because HF/E systems analyses require setting clear boundaries to the system being investigated, we limited the study focus to clinical situations where the decision to initiate EFM had already taken place, and up to the point of escalation, without examining clinical interventions in response to possible fetal deterioration.

Data were collected between April 2019 and March 2020. In each unit, the data was collected both by a human factors specialist and an experienced social scientist. Each researcher completed up to seven ~8-hour days in each maternity unit, conducting day and night observations and interviews with professional staff. Observations focused on the delivery ward, with occasional time spent in the antenatal ward and antenatal assessment clinic to understand upstream processes. Observers sometimes spent long periods of time in one room, or moved through multiple areas, sometimes shadowing a professional. To avoid

imposition of pre-determined categories, no structured observation form was used, but the human factor experts used the SEIPS 2.0 framework to guide their observations. [21, 22, 26]

Interview participants were selected purposively to represent diversity in professional background (midwives and doctors), and different seniority and professional experiences, though availability of staff limited the extent to which selection was possible. Interviews were tape-recorded and transcribed verbatim. Ethnographic data were captured in the form of brief anonymised in situ field notes and later written up in full. Debriefing sessions of the research team were recorded, transcribed, and treated as data alongside the field notes.

We conducted two types of analysis in parallel. The first used the SEIPS 2.0 model to describe the work systems we observed and the interactions of people, tasks, technology, organisational structures, environment and external influences. Human factor specialists coded their observations as well as all interviews, and then related these codes to the SEIPS categories. Second, social scientists coded their observations and all interviews based on the constant comparative method, [27] involving initial open coding of a selection of interviews and observations to guide development of a coding frame that was then applied to the whole dataset. Data were analysed at the site level first, then across sites. QSR NVivo 12 software was used to support coding, management, and retrieval of data.

The team was multidisciplinary from the onset, and the design and conduct of the project involved obstetricians, midwives, HF/E specialists, and social scientists. We held bi-weekly meetings between researchers from the HF/E and social science streams while planning and conducting the research to ensure integration of design and sharing of emerging findings.We also organised multidisciplinary debrief sessions every time a researcher (HF/E or social scientists) had completed their visits in one site. After HF/E specialists and social scientists had completed their initial parallel analysis of the data, we discussed themes and findings collectively to arrive at a synthesis. This prompted further interrogation of the data, until we arrived at a shared understanding.

Written informed consent was obtained from participants to interviews. Oral consent was sought from healthcare professionals and those in labour and their partners before observations. Maternity service user representatives were involved in reviewing the study documents (protocol, leaflets, posters), which were revised following their comments.

Results

Across the three participating units, we conducted 325 hours of observation, and completed 23 interviews (Table 1). In presenting our findings below, we first identify and briefly describe the key SEIPS 2.0 elements (Figure 1), with illustrative quotations presented in Supplementary Table 1. We then integrate our human factors and our social science analyses to explain how

these system components interact, and how these interactions affect the functionality of the system as a whole.

Table 1: Data collected across three sites

	Hours of Observation	No. of Interviewees
Site 1	58hr 35min (Social Science) 65hr (Human Factors)	11 midwives and 3 doctors: 14 total
Site 2	70hr 15min (Social Science) 39hr 30min (Human Factors)	3 midwives and 2 doctors: 5 total
Site 3	42hr 30min (Social Science) 49hr 30min (Human Factors)	2 midwives and 2 doctors: 4 total
Total	**171hr 20 min (Social Science)** **154hr (Human factors)** **325hr 20min**	**16 midwives** **7 doctors** **23 total**

System description

In all three units, those in labour were cared for primarily by midwives on the labour suite. For those deemed “high risk”, EFM using cardiotocography (CTG) was used to track changes in the fetal heart rate. In all three units, midwives were expected to monitor the paper record produced by CTG machines (known as “the trace”) to assess changes and classify deviations from normal using pre-specified criteria. Their interpretations were intended to be recorded on the traces, often using a dedicated ‘sticker’ template that was attached to the trace (Figure 2). Midwives were also expected to seek second opinions (known as “fresh eyes” [28]) from professional colleagues, usually another midwife, every hour, and to make decisions about whether any potentially concerning fetal heart rate patterns required escalation (e.g. to a more senior midwifery colleague or an obstetrician). Obstetricians, including doctors-in-training, specialist and associate specialist doctors, and consultants, were expected to review traces with other clinical information as part of routine rounds and on request by midwives, and to make decisions about whether further clinical intervention (e.g., expedite birth) might be needed.

[Figure 1] – See supplementary file. This figure is based Holden et al. 2013 [22] and on Holden and Carayon 2021 [29]

Figure 2. Example of 'sticker' for recording the interpretation of CTG traces (NB: not from one of the sites we visited, in the interests of confidentiality).

Staffing levels and workload

SEIPS elements: organisation; people; internal and external environment

Staffing levels, including sufficient midwives, obstetricians, and other staff, and in the right role configurations, were of critical importance. However, we identified – for example through posters indicating planned and actual staffing available, as well as through discussions with staff members and observations of handovers – that units were often understaffed or lacking sufficient numbers of staff in the appropriate roles with the appropriate proficiencies. Individual professionals were often dealing with very high workloads, which meant that it was not always possible for a midwife to be consistently present in the room with labouring women. Sometimes, staff who lacked specific experience or expertise were asked to cover vacancies or temporary absences.

Clinical workloads meant that midwives were sometimes unable to attend multidisciplinary CTG meetings, which was where traces from their unit were discussed with the medical team. Staff also reported difficulties in taking breaks, adding to the fatigue and pressure.

> *When you're actually there on the coalface it's really, really tough because you might have another patient, you might have answered the phone, you might have a coordinator on who you don't really value their opinion, […] you haven't eaten, you haven't drunk, you haven't been to the bathroom – they are all the extra factors that make the job really hard. [Midwife, Site 2]*

Availability of well-designed and well-functioning equipment in appropriate spaces

SEIPS elements: Tools and technology; external and internal environment; organisation

Well-designed, well-functioning equipment is fundamental to effective EFM. In none of the three sites was this requirement consistently met. In two sites, there were too few CTG

machines. In all three, machine design and maintenance were often suboptimal. Equipment malfunctions were common and appeared to be related to both defects inherent in the machines themselves and to poor maintenance (Table 2). Routine problems included paper running out or jamming, sometimes at key moments. At one site, we identified two occasions when monitors were not printing the right time or even the right date on the paper.

> *The midwife went back in at this point and when trying to print off the trace accidentally turned the machine off due to confusion over the options. So this was turned off and the trace was lost and then they had to run the test again. [observations, Site 2]*

Challenges also occurred because of variations between machines**,** linked to how decisions were made externally, by manufacturers, and, internally, by procurement decisions, including legacy procurement. Brands, makes and vintages of machines varied within and between sites. How they needed to be handled varied, as did their outputs.

Monitors were variably located, sometimes centrally and sometimes in the room with the person in labour. Central monitoring allowed professionals to keep an overview of the situation across the labour suite and to discuss potentially alarming traces efficiently. But having the CTG machine in the room with the woman brought potential benefits, including the ability to assess the whole picture more easily and to communicate effectively.

Table 2. Issues of availability and functionality of electronic fetal monitoring equipment.

Category	Problem	Consequence
Technical features	Difficulties in getting and keeping a good signal	Midwives holding the electrode in place, (thus diverting resources from other tasks), or asking the mother to keep the electrode in place (limiting her movements)
	Wireless monitors picking up signals from other monitors	Risk of inaccurate appreciation of the situation
	Electrode battery not lasting long enough	Time-consuming efforts to find alternatives, risk of delays in monitoring
	Showing up mother's heart rate instead of foetus's	Risk of inaccurate appreciation of the situation
Human-machine interface	Inadvertently change printing speed	Risk of misinterpreting the trace
	Inadvertently switching off the monitor	Loss of time and data
	Different grids on screen and on paper	Risk of misinterpreting the trace
Supplies	Missing parts (e.g., leads for fetal scalp electrodes)	Time-consuming efforts to find alternatives, risk of delays in monitoring

	Missing consumables (e.g., paper)	Time-consuming efforts to find consumables, risk of delays in monitoring
Procurement	Different machines in a unit printing in different colours or scales	Risk of misinterpreting the trace
	Insufficient number of monitors	Time-consuming efforts to find equipment, risk of delays in monitoring
Maintenance and set-up	Paper jamming	Loss of time and data, delays or interruption to monitoring
	Wrong time or date	Wrong timeline when reviewing the trace
Physical layout	Bulky monitors in small rooms	Cramped workspaces

Clarity about criteria for assessing deterioration

SEIPS elements: external environment; internal environment; people; organisation; tasks

Maternity professionals need to have shared understanding about the criteria to be used to classify CTG traces, along with clear thresholds for making decisions about what might constitute a pattern of deterioration and its significance. Across the three sites, however, we identified lack of consensus on the relevant criteria and thresholds and how they should be interpreted and actioned. Different guidelines were used across the three units, including those of the National Institute for Clinical and Social Care Excellence (NICE [30]) and the International Federation of Gynaecology and Obstetrics (FIGO).[31] A so-called “physiological” approach [32] (without official standing, but promoted through external training events) was also being used by some staff. There was some evidence of hybridised use of criteria, where staff drew on elements of different approaches simultaneously.

Each unit had its own system aimed at supporting review of traces. One example was the mnemonic DR C BRAVADO (Define Risk; C: Contractions; BRa: Baseline rate; V: Variability; A: Accelerations; D: Decelerations; O: Overall impression), which was used to structure thinking about trace interpretation. Some elements of the guidance were encoded in stickers that were attached to CTG traces and used by staff to record their interpretation of the trace, along with any actions taken or required. Guidance was also available on hospital intranets. However, ambiguities about the applicable criteria and thresholds were pervasive. Participants also reported struggling to keep up with changes to guidelines; they had to break old habits and form new ones, as well as deploy changes to their operational systems.

Interviewer: So how do you find these stickers?

Midwife: There are slightly newer ones now, so they are better; but CTG, the evaluation is always changing; and like you've heard on discussion there, they're planning on changing them again. [Midwife, Site 3]

Lack of standardisation contributed to variation and confusion within and between units, so different colleagues were not always working with the shared understanding of what constituted a concerning pattern. Doctors in training frequently moved between units and were sometimes more familiar with a different conceptual model to interpret a trace from that used by their current colleagues. Further variation in the interpretation of traces arose from different individuals' approaches to reviewing traces and making judgements.

Accurate records of interpretations of CTG traces

SEIPS elements: organisation, people, tools and technology

Identifying possible fetal deterioration requires examining CTG traces over time, so making accurate clinical interpretations and recording them over the course of labour is a fundamental work system requirement. However, it was not reliably met in the units in the study. We identified different norms of recording between and within units, with different professionals and teams using different approaches in different ways. For instance, all three sites were using stickers that functioned both as a way of structuring interpretation by providing prompts and as a way of documenting the interpretation (Figure 2). Stickers were more likely to be used by midwives. Doctors were more likely to write in the notes or directly onto the trace, but even this was variable. Doctors did not always record their interpretation (or planned action) in real-time when called for a review, sometimes creating difficulties in later decision-making. Though many professionals valued the stickers, they were also at risk of becoming something of a "tick box" exercise in practice.

When it becomes complicated, when there are issues, is when it's least used the sticker for interpretation. So, when we should be using it the most we use it the least […] It's all lovely for a nice, normal [CTG], we've got lovely notes for normal. When it all goes wrong is when the notes are the least used. [Senior midwife, Site 2]

Support for sound decision-making to recognise deterioration

SEIPS elements: people; organisation; task

Fatigue, familiarity, inaccurate heuristics, cognitive load and limited knowledge are all recognised contributors to flawed decision-making (e.g., inaccurate interpretation of a CTG trace). We identified all of these factors to varying degrees across the units. In part to address

these challenges, all three units were using a “fresh eyes” system, which required midwives to ask another professional every hour to independently review and interpret the CTG trace and record this interpretation on a sticker. Many valued the system, seeing it as an important support.

> *Especially on a night I find when you’re looking at trace and you start to lose that objectivity with it because it’s darkish, you’re tired. But at least we have someone coming in each hour to check, and if you’re getting your proper break relief you again have another person in for a little while just checking you’re okay. [midwife, Site 2]*

“Fresh eyes” was not straightforward in practice, however. It was not always easy to find a colleague to review every hour, especially one who had not seen the trace before. It seemed also that two individuals might inadvertently collude to produce a consensual interpretation, rather than the second individual actively challenging the first interpretation. For example, the midwife in the room often began to present their interpretation before the “fresh eyes” midwife had a chance to look at it, potentially creating a framing effect. One incident that we observed involved a trace that had no accelerations and variability below 5 bpm. It was classified as “normal” by the midwife in the room, even though such a pattern should be seen as concerning. The first midwife gave their interpretation to the “fresh eyes” midwife as soon as they entered the room, and the second midwife classified the trace as “normal” too.

Clinical competence in detecting fetal deterioration

SEIPS elements: Person; task; organisation

Detection of fetal deterioration is a highly skilled activity requiring a very high level of clinical competence, including the ability to appreciate the whole clinical picture in context and to use clinical intuition appropriately. Both individual technical proficiency and collective competence (including clear role differentiation, location of authority, effective teamwork, coordination, and distributed cognition) were necessary to achieve this. Informal learning opportunities were provided through role modelling, conversations between professionals, and norm-setting behaviours. All three sites had mandatory annual online CTG training and annual in-person training sessions and dedicated meetings (including debriefing sessions), but attendance was impacted by under-staffing.

The different roles and duties of midwives and obstetricians were important to the ability to function collectively. Midwives tended to be constantly present with the person in labour and attentive to the trace over long periods, allowing them to detect patterns over time and to gain deep knowledge of a woman’s clinical condition and preferences to identify traces for escalation. Obstetricians’ more episodic engagement enabled different perspectives and forms of clinical knowledge to be brought to bear. Doctors’ behaviours included pulling out the whole

trace to observe the wider picture and see trends or changes in the context of women's physiology and medical and obstetric history.

Regular meetings were held to review decisions that had been taken during previous shifts with the aim of enhancing organisational learning and improvement. However, their quality and openness relied on psychological safety, [33] and some participants indicated that new or junior members of the team could feel judged or singled out, thus potentially undermining the benefits. It was also difficult for midwives to attend these meetings, despite their intended multidisciplinarity, because there was often no cover for their clinical work.

> *If you've got a patient in labour or here, you know, you can't because the meeting can take a good hour and you can't really go and sit down. But they are good, I think they are very, very good. [Midwife, Site 1]*

Communicating concerns and escalation processes

SEIPS elements: person; task; organisation

Communicating concerns about possible fetal deterioration is essential to making decisions about whether any intervention may be needed. Communication practices depended on quality of decision-making at the point of care, shared understanding, and ability to command attention. None of these were straightforward to achieve. In all units, midwives were expected to escalate concerns in the event of a trace classified as 'pathological' and overtly pathological traces were generally escalated without further ado. However, most traces were not obviously pathological, and instead required complex interpretations and judgements that were not easy to make.

> *Well, when the CTG is normal you can be very reassured. When the CTG is abnormal, it can mean a myriad of different things. (...) The decision-making is so complex, (...) I think it only really works in the hands of expert interpretation. [Midwife, Site 2]*

> *So there was a point in the night... a woman had a suspicious CTG, but the midwife said that it was OK okay for now, no action needed, because the results of the fetal blood samples were reassuring (...) But also, almost at the back of their minds, you could see that they were a bit more alert. A registrar and the midwife said, outside the woman's room, 'we all know something's going to happen there'... There was a sense that complications were about to happen. [Observation, site 1]*

Once a decision was made to escalate, the workflow was variable, but typically involved contacting the senior midwife or labour suite co-ordinator, who could then engage an experienced senior doctor. Sometimes, however, in particularly concerning situations, midwives escalated straight to a doctor and informed the coordinator subsequently. In taking escalation actions, judgements about the competence and decision-making ability of colleagues sometimes featured. For example, experienced midwives were sometimes

reluctant to defer to the views of doctors whom they saw as inexperienced, worried that escalation would be frustrated by an incorrect interpretation.

> *Soon after the ward round the specialty trainee came to speak to me and he was a bit flustered or perhaps frustrated was the way to describe it. And he was saying the midwives were putting pressure on him to perform a C-section on the woman in labour. He felt a C-section was unnecessary […] but as the labour wasn't progressing the midwives wanted a section. [Observations, Site 3]*

On the other hand, a major influence on escalation decisions was fear of a cascade of intervention that might be triggered by involving obstetric colleagues. Once a fetal trace began to be escalated, it became increasingly difficult to recover the possibility of a vaginal birth without intervention. Participants explained that there was a very high false positive rate for abnormal CTGs; expediting birth by caesarean in all situations where the CTG was deemed not normal would result in unnecessary intervention, and reduce resource for situations where intervention was needed.

Clearly designed workflows, teamwork, and situation awareness

SEIPS elements: Task, organisation, internal environment

Crucial to being able to mobilise an appropriate response were clearly defined processes, clinical workflows, roles, and tasks, for example to define responsibilities for decision-making, ensuring action and maintaining situation awareness. However, they were variably evident in the units we studied. In all three, the labour ward coordinator played a critical role in monitoring situations, anticipating need, and coordinating responses. This required ensuring that this individual and other key colleagues were kept briefed when concerns were developing in relation to a delivery.

In these decisions and practices, professional hierarchies and experiences, relationships between different professions, personality and personal histories all mattered. Disagreements over the right course of action to take were common, although they varied in content.

> *When new people come along, I find the most stressful time, new doctors, the changeover. I loathe that time. Because when you know someone well and they say '[the trace] is OK', you're thinking, OK, they know. But when someone new comes and says it's okay I'm thinking, do I trust you? It takes a while to build that. [Midwife, site 3]*

Discussion

This study of everyday work on three maternity units affords important understanding of the problems to be solved to improve EFM. [34] [35] Our account of "work as done",[12] combining SEIPS and social science analysis, showed that EFM is a profoundly collective process, involving multiple interactions between people, tasks, tools and technology, organisation, culture, and behaviour,[22] all constituting a single clinical microsystem.[36] We also found that the work systems for EFM appear to be poorly optimised for safety. A particular challenge is that the diverse elements of these work systems are intimately interrelated and interdependent, involving multiple actors who must coordinate activity, achieve shared understanding, make sound decisions in the face of uncertainty and competing considerations, demonstrate respect for those in labour and their partners, and take appropriate actions at the right time. Structural challenges are pervasive, for example in relation to staffing, equipment design and supply, and buildings and facilities. [37] [38] Further complexity is introduced by the contested nature of the evidence underpinning some practices. These findings confirm that EFM is a sociotechnical system involving multiple interdependent elements that may interact in complex ways,[39] and that improvement efforts focused solely on individual practice (e.g. competence in CTG interpretation) are unlikely to succeed on their own. Improving electronic monitoring will require a multi-faceted, integrated, systems approach that draws on evidence-based strategies, including work systems that are purposefully designed, better and clearer guidance and processes, better tools and technologies, and better understanding of people, their roles, and skills.

Some hazards we identified are structural in character and highly consequential, reflecting how work systems for fetal monitoring sit within larger sub-systems that influence what can be achieved locally. For example, sufficient supplies of functioning equipment that reliably record the fetal heartrate is a basic work system requirement, [40] but one that was not consistently met in the units in our study. Redesign of tools and technology so that machines are ergonomically designed, with standard interfaces (e.g., printing and display format) across machines used in each site should be a priority. However, it will require large-scale external as well as internal action, with procurement processes[41] and manufacturers each playing an important role – so will require large-scale coordination and leadership to resolve.[42]

Large-scale coordination will also be required to address many of the structural issues on maternity units relating to sufficient staff in appropriately configured roles, which we found mattered greatly for teamwork, coordination, decision-making and action. For example, detection and appropriate communication of a concern and mobilising an effective response may be difficult in conditions of excessive task loads, availability of staff, fatigue, and cognitive burden. Yet these structural issues were often beyond the scope of control of individual units to resolve easily, given challenges in payment models, staff recruitment and retention, and national policies on workforce.

One obvious target for improvement is the multiplicity of guidelines used between and within trusts, which would benefit from rationalisation and coherence at national level, [43] to avoid the

confusion and inefficiency we found in units. Standardised formal risk assessment tools that have been co-designed with staff and patients and offer clear triggers, thresholds and processes for calling for help are likely to support control of risk, situation awareness and multidisciplinary coordination. [44] Leadership at system level will be needed to achieve the necessary consensus.

Other hazards are, perhaps, more tractable to action in the short-term. For example, though clinical skills are not, on their own, a comprehensive solution to safety risks in fetal monitoring, they remain fundamental as a key socio-technical factor. Accordingly, high quality multi-professional training is critical, [39, 43, 45-47] as are regular multi-professional meetings. [45] A further target for improvement concerns interprofessional relationships on labour wards, which have also been identified in previous research as highly consequential for practices relating to electronic fetal monitoring. [19, 20] Our analysis made clear that just as important as the technical skills of interpretation are “non-technical” skills such as situation awareness, teamwork, communication, decision-making and so on. The available evidence suggests that improvement in clinical and litigation outcomes can be secured in all of these areas through high-quality, high-fidelity training. [48] [47] [49]

Our findings contribute to long-standing debates about EFM ,[50] including questions about whether the equivocal nature of the evidence about whether it “works” arise because of its inherent limitations as a technology or because of challenges in implementation. An important strength of our study is our use of combined HF/E and social science approaches, and its offering of non-clinical ‘outsider’ insights into the nature of the work systems underlying EFM.[13, 51] The SEIPS 2.0 model proved a flexible framework in this diagnosis stage, compared to more structured HF/E approaches.

This study also has limitations. We did not have access to performance or clinical data, meaning that we could not quantify the relationship between the process variations we identified and clinical outcomes or risk control. We collected data in three maternity units. Although we sampled for diversity (size, location), we may have missed important hazards that could exist in other units. More interviews were carried in Site 1 than in the others, which could bias our results (although observations were more equally distributed). Finally, we stopped our investigation at the point of escalation, without looking at timely response and 'rescue'. These are also crucial influences on safety, [52] and will be the focus of future work.

Conclusions

Improving EFM is not simply a matter of producing better guidelines or more rigorous individual training. Instead, it requires understanding that CTG is a practice fraught with socio-technical complexity and interdependencies, and is profoundly collective in character, underpinned by relationships, expertise, and skill. Improvement efforts to address this than focusing solely on individual behaviours. A broader set of influences on safety and their

interdependencies must be considered in creating the conditions for improvement. While some issues may be tractable to local action, others will require large-scale coordination.

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