PPH kits study: photo-based survey

Protocol for work package 2: Mapping current layouts and contents of PPH kits

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# Project team

## Research team

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## Expert Collaborative Group

A multi-professional group comprising 12 invited professionals with backgrounds in maternity care, patient safety, and/or human factors engineering. The group is set up to explore key issues with the research team that arise in the course of the study, with the aim to help ensure that these issues are understood from the full range of perspectives of those affected by them. All group members have agreed on terms of reference for the Expert Collaborative Group. A list of members is provided in Section 7 of this document.

## Sponsor Representative

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# Abstract

**Background:** Post-partum haemorrhage (PPH) is a common obstetric emergency, which can lead to complications in more than one in 100 births. Treatment delay is highly consequential for outcome: deaths from PPH peak at 2–3 hours after childbirth. Central to optimising the management of PPH are use of evidence-based practice, rapid mobilisation of healthcare professionals, and ready access to required clinical supplies. But even in high-income settings such as in the UK, the supplies needed to manage a PPH emergency are not always reliably to hand when required. One approach to enable rapid mobilisation following PPH is to contain all necessary equipment and supplies together in an emergency kit. In the UK, such PPH kits are currently designed and implemented locally by individual maternity units. As a result, there is a risk that some PPH kits are sub-optimally designed, impose supply chain costs, increase waste, or create missed opportunities for economies of scale. Further, the resulting variation introduces the possibility of error, confusion, or lost time as staff attempt to locate resources in an emergency situation, especially when professionals work across different maternity units.

**Aim of PPH kits study**: We have developed a programme of work (PPH kits study) that includes mapping and understanding the layout (e.g. box, bag, trolley), contents, and re-stocking systems currently used for (e.g. medication, fluids, catheter) of current PPH kits across maternity units in the UK, using observations and interviews in maternity units and a photo-based survey method. The PPH kits study aims to use participatory methods and co-design principles to inform guidance that help maternity units in standardising and improving their PPH kits.

**Current work package:** This work package of the PPH kits study aims to characterise variation in the layout and content of PPH kits of a representative sample of maternity settings in the UK (including approximately 20 to 40 maternity units), using a photo-based survey that engages maternity professionals on an online collaboration platform (Thiscovery). A particular advantage of this approach is that photos can provide details that a written list of objects would not offer; such detail is crucial to ensure a comprehensive understanding of variation. We will invite relevant maternity professionals from purposively selected maternity units to register on Thiscovery, upload photos of PPH kits and their contents, and answer a small number of questions about the PPH kits. Data analysis will comprise: identifying and labelling kit layouts (e.g. box, bag, trolley) and content items (e.g. medication, fluids, catheter) in each photo, calculating the proportion of each kit layout and content item across the sample, and explore relationships between maternity unit characteristics and PPH kit type and contents. Findings will feed into a next work package that aims to co-design potential prototypes of, and/or guidance for, a standardised PPH kit.

# Background

Postpartum haemorrhage (PPH) is an obstetric emergency responsible for 100,000 maternal deaths worldwide.1 A major PPH (more than >1000ml of blood) complicates 1.2% of all births — and in many countries the incidence of PPH is rising to even higher levels than 1.2% — but most maternal deaths related to PPH can be avoided through effective clinical management.1 2 Treatment delay is highly consequential for outcome: deaths from PPH peak at 2-3 hours after childbirth.3

Treatment requires prompt initiation of several simultaneous actions including uterine massage, intravenous fluid resuscitation, and administration of medication (uterotonics to contract the uterus and tranexamic acid to treat major haemorrhage). Every 15 minutes of delay reduces the survival benefit by about 10%.3 It is thus important that health care professionals are able to mobilise quickly, use evidence-based practice, and have ready access to the appropriate supplies. But even in high-income countries, the equipment and other resources needed to manage a PPH emergency are not always reliably to hand at the time of need.4

## Postpartum haemorrhage kits

One solution, based on sound ergonomic principles, is that PPH kits should be routinely available to provide professionals with all the medicines, supplies and instruments needed to manage a PPH in the location where it occurs. Where PPH kits have been introduced, they have been associated with improvements in outcomes in maternity care across all resource settings.5 6 7..

In the UK, the layout and contents of the kits are currently agreed locally by individual maternity units. In consequence, they vary from one maternity unit to the next. The kit itself may take the form of a PPH box, a dedicated PPH trolley, specific drawers inside a general maternity emergencies trolley, or a variety of other forms. The contents of the kits are also variable — for instance, some include medicines while others do not, and the various kits are packed and stacked in different ways. Some kits incorporate a treatment algorithm to guide the clinical team in the steps required to manage the emergency, including medication dosages, while others lack such a guide. Other factors that may influence the layout and contents of PPH kits include the size and type of unit and the proportion of different modes of delivery in the unit (i.e. spontaneous vaginal, assisted vaginal and caesarean birth).

The variation in layouts and contents of the kits incurs a learning overhead as professionals move between maternity units. Variability also introduces the possibility of error, confusion or lost time as staff attempt to find and use resources in an emergency situation, especially when professionals work across different maternity units. There is a risk that some emergency boxes are sub-optimal in layout and/or contents, since local teams do not have access to high quality ergonomics expertise. Additionally, kits are typically produced and re-stocked by staff in the units themselves, but defects in supply chains may increase waste or introduce risks of delays in treatment if the kit has not been fully re-stocked and is lacking vital equipment or medication when needed. Given these challenges, a recent World Health Organization-led systematic review of supply kits for antenatal and childbirth care recommended further research in this area.8

## Standardisation and its challenges

One response might be to seek standardisation of PPH kits, which would be in line with some current thinking about how to address many of the challenges facing quality and safety in healthcare.9 10 Broadly defined, standards are specifications of rules, guidelines or characteristics for designing products or carrying out activities.11 Standardisation has a promising role in reducing error,12-14 removing unnecessary variation,13 15 reducing uncertainty in clinical interactions,16 and potentially allowing for more personalised care (as staff do not have to invent and improvise continually). Standardisation reduces complexity and at the same time gives room for the best care for the patient and their partner. But healthcare remains characterised by uncontrolled profusion of everyday practices and objects. Highly localised development, combined with delayed maintenance and de-implementation barriers (see below), mean that these practices and objects may persist over long periods unless major change is purposefully introduced. One example was the entropy of crash call numbers across the NHS, which persisted until the introduction of the standard 2222 number in 2004.17 Many more basic processes might benefit from being standardised or harmonised, especially as these everyday objects and practice may embody a variety of values and assumptions and may be highly consequential for practice.18 To date, however, there are few well-established methods for achieving standardisation of important everyday, low-tech clinical objects such as PPH kits.

This is important, because standardisation, which Timmermans and Epstein describe as “a process of constructing uniformities across time and space, through the generation of agreed-upon rules”,19 comes with its own challenges.9 Standards are defined and implemented through complex sociotechnical processes requiring multiple kinds of purposeful effort during development, implementation and maintenance stages.9 19 The challenges mean that sometimes interventions and solutions are left up to local innovation when they should be standardised, or at a minimum harmonised, across the NHS.20 But imposed top-down solutions are no panacea either. Standards are not implemented in a vacuum; they always have to fit into an ecology of pre-existing systems, norms, behaviours, and established practices,19 with multiple networks of stakeholders, specific constraints and distinct challenges.21

## Standardisation and de-implementation

Standardisation often involves local de-implementation, which is rarely straightforward.22 Although the study of de-implementation in healthcare is in its infancy, various challenges have been identified in de-implementing existing practices with a view to their replacement with standardised, evidence-based alternatives.23 These challenges include financial investments in existing practices, personal emotional investment in particular practices that have been locally developed, and the habituation of practitioners to an existing way of working.24 In some settings, there may be more or less vested interests in maintaining the status quo.25 Moreover, not all de-implementation challenges are the same: the precise nature of what needs to be changed (whether a small component in a wider system that can be relatively easily substituted, for example, or a completely different way of doing things that implies shifts in the wider socio-technical infrastructure) may be relevant.22

A major challenge with many present approaches to healthcare improvement (including standardisation) is that staff may feel the improvement is “done to” rather than “with”. This becomes particularly visible when they are asked to implement a one-size-fits-all improvement solution that may not be customised to the particular clinical processes that staff are trying to address, or when the proposed solution has been designed without their participation, appears inferior, or will be burdensome to introduce. Establishing the nature of any problem and how it is perceived by the various stakeholders, and then co-designing the solutions, is likely to lead to better design and ease of implementation.26 27

## Aims of the PPH kits study

We have developed a programme of work (PPH kits study) that addresses the challenges of sub-optimal and varying PPH kits and the lack of engagement and co-design with staff in the improvement of PPH kits. The PPH kits study has four aims:

1. To map and understand the layout, contents and re-stocking of PPH kits currently used in maternity units in the UK.
2. To use participatory methods to identify priorities of stakeholders for layout and contents of PPH kits, including co-designing solutions for improving PPH kits.
3. To produce guidance about designing optimal PPH kits for UK maternity units.
4. To produce learning about the application of participatory approaches and user-centred methods to the development and standardisation of everyday clinical objects.

# Current work package

## Aim of work package 2 (PPH kits photo-based survey)

Work package 1 of the PPH kits study involved a work system analysis using observations and interviews in a small number of purposively selected maternity units and settings. That study received ethics approval from the HRA and the North West Haydock REC (reference 20/NW/0248). Work package 2 builds on these findings, as presented below.

Work package 2 of the PPH kits study aims to characterise variation in the layouts and contents of PPH kits of a representative sample of maternity settings in the UK (including approximately 20 to 40 maternity units). It uses a photo-based survey that engages with maternity professionals on a secure online collaboration platform ([Thiscovery](https://www.thiscovery.org/about/)), developed by THIS Institute and hosted by THIS Labs.

The planned end date for the study – including data collection and data quality checks -is aimed to be at the to be the end of 1 November 2024.

## Considerations for work package 2

Previous attempts to collect data on everyday objects, such as PPH kits, in the NHS have often been limited in scale. For instance, a study to develop an ideal critical care transfer bag relied on a list of items recommended by the Intensive Care Society and a review of the contents of bags used in just three settings.28 Large-scale online engagement is one way in which the challenge of scale may be addressed. It can provide large volumes of data covering many geographical locations, rendering what may otherwise be daunting or expensive exercises to become more efficient and feasible. Examples including Flu Near You,29 uBiome30 and other microbiology studies (MetaHIT, Pathomap)31, the MapMyHeart challenge to map cardiac defibrillators,32 and the Flint Water Study, where large numbers of participants who were concerned about their water quality worked with university researchers who tested samples provided by Flint residents.33

Photography is often used in large-scale engagement as a means of data collection, with the involvement of public participants to gather large volumes of observational data.34 35 The emergence of new technologies such as the development and uptake of smartphones has provided new opportunities for such projects to utilise participant-driven photography in innovative ways.35 36 37 In the social sciences, photos have been used as a way of collecting data for number of years,38 39 and are becoming an increasing feature of health research,40 41 42 though methodological considerations when using participant-taken photos must be borne in mind to ensure data is of the required quality.43-47 A range of strategies and interventions can be implemented to help ensure high quality, accurate and valid data from photo uploads and that can help support an engaging and user-friendly interface. These for example include assisting participants in contributing high quality photos via website or app-based interfaces, including clear instructions on how to capture, upload and label a photo, and efficient methods to review uploaded photos by trained analysts. We have used these considerations in the design of this work package.

## Methods for work package 2

### Setting

The work package’s study setting involves a representative sample of maternity units and settings in the UK, where relevant staff will be invited to make photos of their PPH kits and upload these as part of a survey on [Thiscovery](https://www.thiscovery.org/about/). Thiscovery can be accessed on PCs, phones, tablets and other devices using the following link: [www.thiscovery.org](http://www.thiscovery.org).

We aim to collect data on PPH kits from 20 to 40 units that are representative of the approximate 280 maternity units across England, Northern Ireland, Scotland, Wales. An audit of maternity units (National Maternity and Perinatal Audit) or similar source will be used to inform initial sampling of maternity units in England, Scotland and Wales, while other sources will be used to gauge characteristics of maternity units in Northern Ireland.48 49 50 A purposive approach will be used to select a representative sample of units to invite to take part in the study, including representation of the various unit types (free-standing midwifery, alongside midwifery, obstetric unit), unit sizes (based on annual births), and countries (England, Scotland, Wales, North-Ireland) across the UK.

The CRN will be asked to support sending a study information package to the Research and Development (R&D) offices of NHS trusts that include the units selected to be invited to take part. The research team will generate a list of purposively sampled units whose trustsprovided their formal confirmation of capacity and capability. We will confirm representativeness of this list with maternity experts with extensive insight into the UK maternity landscape (if needed, the procedures above are repeated to generate a representative sample of units). Relevant professionals from the list with representative maternity units will be invited to participate in the photo-based survey (see Recruitment).

### Participant criteria

Eligible participants will be professionals from invited maternity units who are directly or indirectly involved in the use of PPH kits, including but not limited to Practice Development Midwives and Research Midwives.

### Recruitment

Networks of the project team, including (but not limited to) the nation-wide PROMPT Maternity Foundation and the Practice Development Midwife networks, will be used to contact and invite potentially eligible participants from the maternity units selected to take part. Recruitment will primarily target (but is not limited to) Practice Development Midwives and Research Midwives. Individuals in these roles – as findings from work package 1 showed – are often best positioned to participate in photographing the PPH kits and answering survey-based questions about it. They are likely to have some allocated time free of clinical duties when they would be able to participate and may be the ones most informed about the layout and contents of the PPH kit.

As shown in step 1 of Figure 1, prior to taking part, invited individuals will be asked to:

* read information about the study provided on a website,
* register on the Thiscovery platform by providing their name and e-mail and accepting the Thiscovery [terms and conditions](https://www.thiscovery.org/about/)
* use the platform to read the details of an online participant information sheet (see Appendix 2), , and complete an online consent form (see Appendix 3).

Invited individuals are given up to six weeks to consider taking part, ask questions, and – if they decide to participate – complete the photo-based survey.



**Figure 1.** Participant flow

### Data collection

Following registration on Thiscovery, confirming their eligibility and completing the consent form (Figure 1), participants will be presented with online instructions which and how photos of the kits should be made (Appendix 4). The instructions will include a step-by-step guide about the photos that are required. Participants will then be asked to use a mobile phone or tablet to take around ten photos of a PPH kit on their unit, in accordance with the instructions.

Following, participants are asked to log in again to the Thiscovery platform using the mobile phone or tablet they used to make the photos (Figure 1). They will be guided through a set of questions that will involve uploading the photos and answering associated questions (Appendix 5). The questions concern the layout of the PPH kit (box, trolley or other type of kit), where it is kept, and what contents it has. Participants are also asked to complete a few short questions about the characteristics of the unit where the kit was photographed.

We estimate that the participant will require up to 60 minutes in total to complete all steps outlined in Figure 1, which can be conducted over separate, shorter time blocks.

### Data analysis

The analysis of photos of PPH kits will consist of four stages: 1) data cleaning and content review, 2) coding photo contents, 3) description of layout and contents, and 4) exploration of relationships between maternity unit characteristics and PPH kit layouts and contents.

First, a research team member will clean the data and assess its completeness, including reviewing the data to assess the proportion of missing photos or unanswered questions. This process will also include checking for any identifying information in each photo (for example a trust logo) and redacting this data (see Section 5.3 below).

Second, one or more trained analyst/s from the research team will identify the content of the photos and record this information in a pro forma. It is likely that some items are difficult to identify; consequently, there will be an option to mark items as unknown. As a quality check, a small sample of photos will be selected for review by Expert Collaborative Group members (Appendix 1) with relevant clinical expertise. The photos will be presented using a slidedeck during an online meeting (the slidedeck is not shared outside of the meeting). When discussion about coding of the item remains unresolved, a senior researcher and clinician from the research team will adjudicate.

Third, the research team will quantify various properties of the PPH kits, such as the type of kit (bag, box etc.), the number of kits that are ­accompanied by a PPH algorithm, the type of organisation used (if any), the proportion of kits in which a particular item is found, and the number of items in each kit. Data may also be described using narrative or diagrams in terms of what forms of grouping/organisation exist (e.g. by stage of care, by type of equipment), including potential benefits and disadvantages of each. Where items have been grouped, analysis will identify the relative co-occurrence of items in different stages/compartments/panels of the kit (e.g. co-occurrence of tape and cannulas).

The fourth stage of analysis will use descriptive measures to explore relationships between maternity unit characteristics and PPH kit layouts and contents.

# Ethical and regulatory considerations

## Peer review

The research team (see page 1) and two other senior investigators from THIS Institute have contributed to the development and peer review of the study protocol.

## Risk assessment

The project team has developed a risk assessment (including potential risks and measures to mitigate risks relating to ethical considerations), which will be reviewed regularly to proactively assess if additional or alternative risk mitigation measures may be needed. One important consideration is the readiness of PPH kits in the maternity units. The data collection process requires that the PPH kit is unpacked for a brief period, such that its contents can be photographed. There is a possibility that the kit is required during the time it is partially unpacked. To mitigate this risk, participants will be advised to photograph a spare/secondary kit if available. If the unit only has one kit, participants will be advised to be aware of the potential need for the kit (i.e. the end of second stage labour) and avoid conducting the photo-taking task in these periods. Additionally, the photo-taking task has been designed to be short (less than 30 minutes), for example by instructing for items to be recorded in group shots rather than as individual items. The risk assessment also considers data management relating to identifiable information (as further detailed below).

## Data management

Participants are asked to register on the secure Thiscovery platform by providing their name and e-mail and accepting the Thiscovery [terms and conditions](https://www.thiscovery.org/about/). They can then consent to take part in the study (see section 4.3.3).

For each participant who consents to take part, all their activity in the project will be associated with a universally unique ID (UID) which, for the duration of the project only, will be linked to the participant’s personal details (name and e-mail address) in the Thiscovery database hosted by Amazon Web Services (AWS). Once consent is complete, the participant will be able to view the survey pages to upload photos. When an individual logs into Thiscovery and completes the photo upload task, no personal data is transferred to the data collection site. Instead, a universally unique ID (UID) is generated. The link between an individual’s personal data (name) and their UID is held in AWS, separated from the other research data. Anonymisation link keys are held on AWS servers only. Access to the Thiscovery database will be limited to the Thiscovery technical development and support team.

Questionnaire data, which will include participant job role and maternity unit name, will be treated as personally identifiable data (PID). This data will be stored in one of the University of Cambridge safe havens, which is covered under the NHS England Data Protection Toolkit*.* Photographic data will initially be stored on AWS and linked to participant only by the UID. Once the research team have checked for (and if needed redacted) any identifying information (e.g. any information about the participant or the trust where the photos were taken), then the photographic data will be stored on a secure research drive at the University of Cambridge, which is accessed only through password-protected devices (e.g. laptops managed and owned by the University of Cambridge).

The Chief Investigator will act as the custodian for the data generated by the project. Any links between the personal data held in Thiscovery and the data generated by the project will be destroyed two years following the end of the project. This will be done by deleting users' project-specific user IDs in the Thiscovery database. Personal data used to register for Thiscovery will remain in the Thiscovery personal data stores, as set out in the Thiscovery terms and conditions. Users can de-register and withdraw their data from Thiscovery at any point by emailing help@thiscovery.org.

## Patient and public involvement

The study will be supported by a multi-disciplinary Expert Collaborative Group (ECG) which will include representation from a national patient safety lead in maternal and neonatal care, NHS professionals and researchers (see Appendix 1). The role of the ECG will be to provide advice as the study progresses and ensure that a range of stakeholder perspectives are considered. Throughout the study we will consider the perspectives of those with lived experience of labour and their birth partners,51 52 by drawing on the extensive work on the perspectives of women and their birth partners in studies of obstetric emergencies carried out by THIS Institute and its collaborators (<https://www.thisinstitute.cam.ac.uk/themes/maternity/>).

We have identified opportunities in the dissemination of the study’s results where broader involvement of those with lived experience of labour, their birth partners and advocacy organisations can play a meaningful role. We will work with these stakeholders to raise awareness of the issue of postpartum haemorrhage and the role that effective systems in healthcare delivery play in preventing them and managing them well when they occur.

The governance structure at THIS Institute includes an engagement and involvement advisory board. Their role is to provide strategic oversight and guidance on our engagement and involvement work with patients, public and NHS staff, ensuring that the research we undertake is aligned with their needs. As the study progresses and challenges arise, we can call on their expertise as required.

Feedback about the study will be provided to participants at various stages, with results being made available to research participants on THIS Institute's website (<https://www.thisinstitute.cam.ac.uk/>).

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# Expert Collaborative Group Members

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| Expert collaborative group members |
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| Steve Summerskill | Reader in Design | Loughborough University |

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