



# BMJ Open Characterising and describing postpartum haemorrhage emergency kits in context: a protocol for a mixed-methods study

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## ABSTRACT

**Introduction** Postpartum haemorrhage (PPH) is an obstetric emergency requiring prompt and accurate response. PPH emergency kits containing equipment and medications can facilitate this kind of intervention, but their design and contents vary, potentially introducing risk of confusion or delay. Designs may be suboptimal, and relying on localised kit contents may result in supply chain costs, increased waste and missed opportunities for economies of scale. This study aims to characterise contextual influences on current practice in relation to PPH kits and to describe the range of kits currently employed in UK maternity units.

**Methods and analysis** This mixed-methods study comprises two phases. The first will use field observations and semistructured interviews to research PPH kits in a small number (3–5) of maternity units that will be selected to represent diversity. Analysis will be conducted both using an established human factors and ergonomics framework and using the constant comparative method for qualitative data analysis. The second phase will use a research and development platform (Thiscovery) to conduct a crowdsourced photography-based audit of PPH kits currently in use in the UK. Participants will tag images to indicate which objects have been photographed. Quantitative analysis will report the frequency of inclusion of each item in kits and the content differences between kit and unit types. All maternity units in the UK will be invited to take part, with additional targeted recruitment strategies used, if necessary, to ensure that the final sample includes different maternity unit types, sizes and PPH kit types. Study results will inform future work to develop consensus on effective PPH kit designs.

**Ethics and dissemination** Approval has been received from the UK Health Research Authority (project ID 274147). Study results will be reported through the research institute's website, presented at conferences and published in peer-reviewed journals.

## INTRODUCTION

Postpartum haemorrhage (PPH) is an obstetric emergency responsible for 100 000 maternal deaths worldwide, with the majority of these in low/middle-income countries.<sup>1</sup> The incidence of major PPH (more than

## Strengths and limitations of this study

- Field observations from the perspectives of human factors and ergonomics, and social science research will be used to investigate contextual influences on postpartum haemorrhage (PPH) kit use.
- For ethical reasons, PPH emergencies will not be observed directly, thereby potentially limiting insight into real-life use of kits.
- Transferability of findings from field observations may be limited by the small sample size.
- Crowdsourcing photography methods will offer an innovative and potentially engaging means of auditing the types and contents of PPH emergency kits in the UK for the first time.
- There is a risk of some sampling bias associated with the audit as participation is voluntary and may be affected by the characteristics of maternity units.

1000 mL of blood) is rising in high-income countries, now complicating 1.2% of births.<sup>2,3</sup> Most maternal deaths related to PPH in health-care settings can be avoided through effective clinical management.<sup>1,3</sup> This involves 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).

Treatment delay is highly consequential for outcome: deaths from PPH peak at 2–3 hours after childbirth.<sup>4</sup> Thus, for example, although tranexamic acid (an antifibrinolytic) improves survival, it must be given early—within 3 hours.<sup>5</sup> Every 15 min of delay reduces the survival benefit by about 10%.<sup>4</sup> It is therefore important that healthcare 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 are

not always reliably available in an accessible form at the time of emergency.<sup>6</sup>

### PPH kits

One solution, based on principles from ergonomics, is that PPH kits that collate all medicines, supplies and instruments needed for the immediate response to a PPH should be readily available as soon as an emergency occurs. The advantage of a preassembled kit is that time is not wasted searching for, and retrieving, individual items, allowing the response team to focus on clinical tasks. Where obstetric emergency kits have been introduced, they have been associated with improvements in outcomes in hospital-based maternity care,<sup>7,8</sup> and where deployed as part of training programmes, reductions in maternal mortality of 34% have been reported.<sup>9</sup>

An emergency kit may include cannulation equipment and intravenous fluids for administering infusions, blood bottles for transfusion requests, a urinary catheter and medications. However, there is currently no standard design for kits or their contents: they may take the form of a PPH box, a dedicated PPH trolley/cart, specific drawers inside a general maternity emergency trolley and a variety of other forms. The various kits are packed in different ways and the contents vary, for example, some include medicines, whereas others do not. Some kits incorporate a treatment algorithm to guide the clinical team in the steps required to manage the emergency, including medication dosages and a documentation pro forma, but these are not ubiquitous or standard.

In the UK, the design and contents of the kits are currently agreed locally at individual maternity unit level, and they tend to vary from one unit to the next. This kind of variation is likely to impose a learning overhead as professionals move between maternity units and introduces the possibility of error, confusion or lost time as staff attempt to find and use resources in an emergency situation where they are unfamiliar with local practice. There also is a risk that some emergency kits, or the supply chains needed to ensure their functionality and availability, may be suboptimal because local teams do not typically have access to specialist design and ergonomics expertise.<sup>10</sup> 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.<sup>11</sup>

### 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.<sup>12,13</sup> Broadly defined, standards are specifications of rules, guidelines or characteristics for designing products or carrying out activities.<sup>14</sup> Standardisation has a promising role in reducing error,<sup>15-17</sup> removing unnecessary variation<sup>16,18</sup> and reducing uncertainty in clinical interactions.<sup>19</sup> Standardisation reduces complexity and helps unambiguous, routine actions to

be taken and, when well designed, allows flexibility to deliver the best care for the woman and her partner. But healthcare remains characterised by often highly localised development of processes and procedures and subsequent maintenance through inertia and deimplementation barriers. There are few well-established examples of large-scale standardisation of important everyday, low-tech objects, such as PPH kits.

Attempts to standardise are often challenging.<sup>12</sup> Standards are defined and implemented through complex sociotechnical processes requiring multiple kinds of purposeful effort during development, implementation and maintenance stages.<sup>12,20</sup> 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 National Health Service (NHS).<sup>21</sup> But imposed, top-down solutions are no panacea either. Standards are not implemented in a vacuum; they need to fit into an ecology of pre-existing systems, norms, behaviours and established practices,<sup>20</sup> and multiple networks of stakeholders and specific constraints.<sup>22</sup>

Imposing top-down standardisation without sensitivity to heterogeneity of practice and local work system interactions is unlikely to be well-received or sustainable.<sup>23</sup> For instance, some variability in the design and contents of PPH kits may be linked to local context, including the size and type of unit. Improvement efforts that propose standardisation should therefore be based on a sound analysis of work systems and context of use.<sup>24,25</sup> Localised designs may be understood as an organic development in response to the environment, and understanding these environments can offer valuable insights into design constraints (eg, local configurations of physical space and workforce) that are crucial to performance and safety. Analysis of how these factors interact in daily practice lays the foundation for informed design.<sup>26</sup>

### Understanding current practice

The discipline of human factors and ergonomics (HFE) studies the interaction between people and their work environment.<sup>27</sup> One of its core tenets is that any intervention effort should first invest resource in understanding how tasks are conducted in practice, in contrast to how they are documented or prescribed.<sup>28,29</sup> Bringing a non-clinical 'outside' view to give voice and support to the 'inside' reality of work might be of particular value in delineating where differences between prescription and practice are found.<sup>30,31</sup> Another principle of HFE is that of developing solutions in partnership with the end-users. Documented procedures provide a starting point for describing a task, but it is the adaptations and workarounds that reveal what makes a task-equipment combination 'work' across a range of scenarios.<sup>32</sup> Detailed analysis of work systems using HFE methods is therefore likely to be of benefit.

A second important and complementary methodological approach to understanding work systems involves

the use of qualitative techniques drawn from the social sciences, specifically observations and interviews. These methods can be used to access people's points of view and can allow for an exploration of the normative, cultural and organisational features that can influence a work system,<sup>33</sup> including how social relations are mediated and produced through everyday objects and technologies.<sup>34–36</sup> In addition, it draws on literature that highlights how standardisation can be very much about relationships, values and judgements.<sup>20 37</sup>

This kind of detailed work at unit level can yield deep insights into the nature of work systems and the influences on them, but understanding of practice at scale is also needed. Audit-based methods offer an efficient means of describing what is happening in a large number of units.<sup>38</sup> However, traditional forms of data input (eg, surveys requiring structured responses or text) are not well suited to scenarios where the requirement is to gain a visual understanding of a piece of equipment or kit, and where solely text-based descriptions would be tedious to complete or prone to error.

### Crowdsourcing

Crowdsourcing, using large numbers of people to help gather, process or interpret data, is rapidly becoming established as a potentially effective, efficient and engaging way of conducting research and audit. Crowds can provide large volumes of data covering many geographical locations, rendering what may otherwise be daunting or expensive exercises more efficient and feasible. As an added benefit, such approaches can promote dialogue between researchers and citizens, which can help members of the public become more involved in research and make research more democratic.<sup>39</sup>

Crowdsourcing has now been used in a range of academic disciplines.<sup>40–45</sup> Photographs have particular value in such projects.<sup>46 47</sup> In the social sciences, images have been used as a way of collecting data for a number of years<sup>48 49</sup> and are increasingly a feature of health research.<sup>50 51</sup> The emergence of smartphones has provided new opportunities to use participant-driven photography in innovative ways,<sup>47 52–54</sup> though it is important to ensure that data are of the required quality.<sup>55–58</sup> This may be achieved, for example, by developing a clear understanding of the user's task steps, providing instructions and training on how to collect the data and use the upload platform, and automated input into photo labelling. It is also important to ensure that data are sourced from a sufficient range of sites rather than a limited number, as has happened in previous studies.<sup>59</sup>

### Aim

The aim of this study is twofold:

1. Characterise the contextual influences on current practice in relation to PPH emergency kits.
2. Comprehensively map the current range of PPH kits and contents currently in use across UK maternity units using photography-based audit.

## METHODS AND ANALYSIS

The study will be conducted in two phases: the first will combine the use of human factors and qualitative methods in a small number of units to characterise work systems and contextual influences relevant to PPH kit use; the second will use crowdsourcing methods to audit and describe the range of kits currently in use. The phases will run in sequence, the first phase followed by the second (figure 1).

### Patient and public involvement

The study will be supported by a multidisciplinary Expert Collaborative Group (ECG), which will include representation from women who have experienced PPH and their partners, as well as NHS staff and researchers. The role of the ECG will be to provide advice as the study progresses and to ensure that all stakeholder perspectives are considered.

### Phase I: work systems and contextual influences

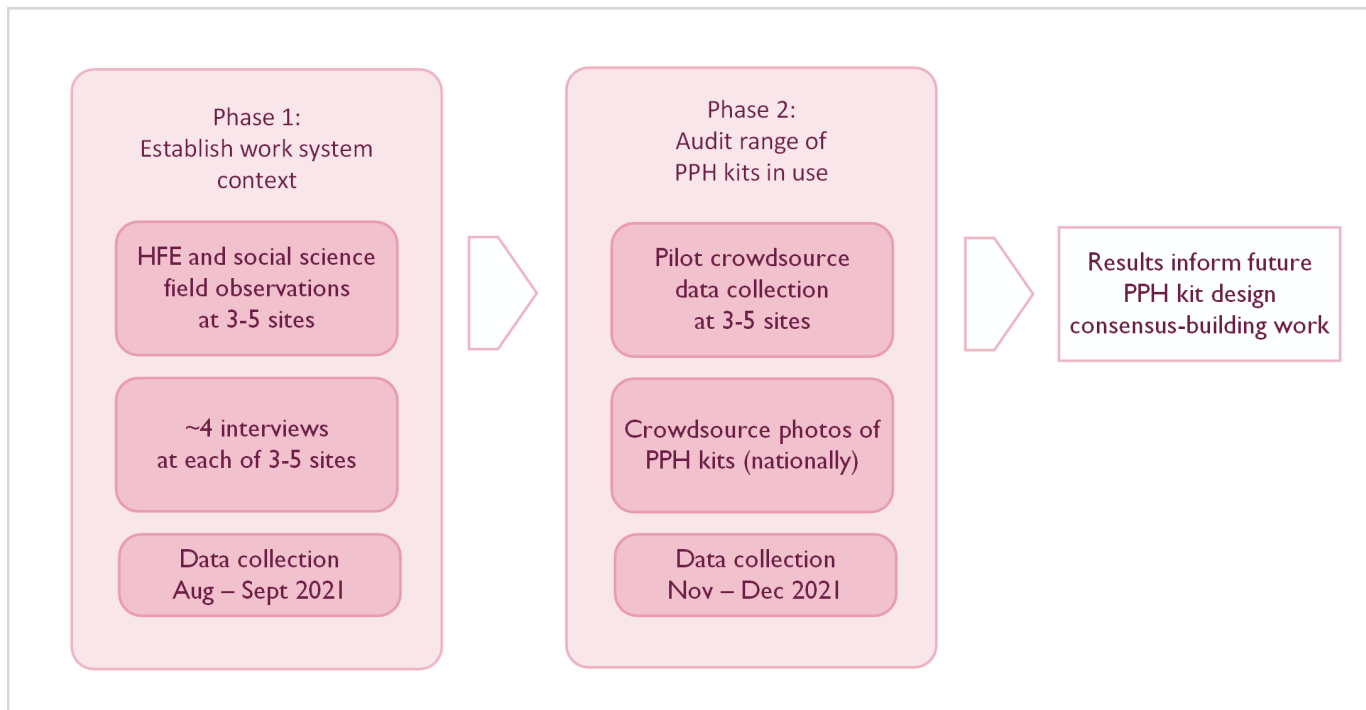
#### Data collection

We will conduct field observations and semistructured interviews with healthcare professionals in three to five maternity units in England. Two researchers, a social scientist and a human factors engineer, will collect data over a period of 2–4 days in each unit (either together or at different times). Observations will be made over 8-hour periods during day and night shifts.

The field observations will be undertaken to collect data about the social, organisational and technical features of using, packing, checking and restocking PPH kits. Participants will be asked to walk through a PPH emergency response and access the kit items as they are required. This will involve moving around the workspace, indicating storage locations, and unpacking and restocking items. When doing this, the researchers will check with staff in real time about entering any clinical areas to ensure it is appropriate and acceptable at that moment. Observations will be recorded in a notebook in the form of brief anonymised field notes; at the end of each fieldwork day, researchers will have the option of dictating and recording their notes in full using an encrypted voice recorder for later transcription or writing them up manually.

A pro forma will be used by the human factors engineer to survey the work system based on the Systems Engineering Initiative for Patient Safety (SEIPS) model, which offers a well-established framework that makes explicit the interaction between five work system components in healthcare settings: person(s), task, tools and technology, organisation and environment.<sup>60</sup> This pro forma (see online supplemental material 1) will be used to document the interaction between the different SEIPS components, particularly the tasks associated with PPH kits. Observations by the social scientist will explore how the routines of checking and stocking the kits are shaped by role expectations and social norms.

We will also identify system components that might be relevant to data collection in phase II to inform, for example, the development of audit instructions. These will include the technology available (eg, Wi-Fi network



**Figure 1** Study overview, dates and associated methods. HFE, human factors and ergonomics; PPH, postpartum haemorrhage.

coverage), environmental factors (eg, light levels) and organisational constraints (eg, work time available for such activity, policy on mobile phone use and photography in clinical areas).

During each site visit, we will conduct around 4 interviews of around 45 min each with staff who use or have responsibility for PPH kits, meaning that up to 20 interviews will be conducted across the study (3–5 sites). Purposive sampling will be used so that at least one participant per site will be a clinician with experience in using the PPH kit for clinical care and at least one participant per site will be a person responsible for checking, packing and/or restocking the kit. We will use the principle of ‘information power’,<sup>61</sup> which, to determine the final size of the sample, assesses the variety of experiences and views, and examines sample specificity, use of established theory, quality of dialogue and analysis strategy in light of the goals of the study.

Each participant will be interviewed either by the social scientist or by the human factors engineer. The social scientist’s interviews will be centred on the emotional, ethical, cultural and organisational factors; the human factors engineer will be focused on technical aspects that influence the use of PPH kits. Two interview guides of around 15 questions each have been developed from the experience of hospital fieldwork and reviewed by the clinical co-investigators and the principal investigator. The guides include questions on clinical practice, for example, ‘Do you always conduct the task with respect to the PPH emergency kit in the same way? How and why does the task vary?’ and on organisational influences, for example, ‘Can you think of a time when you have changed

practices and/or equipment with regard to managing PPH? Why did the change happen?’ All interviews will be audio-recorded on an encrypted voice recorder (with the participant’s consent), transcribed verbatim and anonymised. Supporting documentation (eg, PPH kit checklists) will be requested as required.

### Study setting

The study setting will be maternity units in England. A minimum of three and a maximum of five maternity units will be included in phase I. They will be selected purposively based on unit size (eg, large, medium, small) and the design of their PPH kit (eg, box, trolley). We will include an example of a free-standing midwifery unit in which the unit is separate from an obstetric unit. The objective of this sampling strategy is to look for diverse examples of system-level factors that influence the design and contents of PPH Kits.

We will conduct the same research activities in each participating site in phase I. In each site, we will identify a local collaborator, who will be an individual in a relevant senior position. This individual will be our main point of contact during the setting up of the study (eg, obtaining local permissions to run the study) and will be a conduit for informing staff about the study, identifying participants and providing study information.

### Data analysis

Data analysis will run alongside ongoing fieldwork and will be conducted in two stages. In the first stage of analysis, the social scientist and the human factors engineer will adopt different but complementary approaches. The

human factors engineer's analysis will be conducted from a sociotechnical systems perspective, which describes the interactions and variations between person, task, equipment and environment using task analyses as a basis; the SEIPS framework will be used to structure the analysis.<sup>60 62</sup> Observations will be subcategorised under the framework's five headings, with a sensitivity to factors that are task enablers or barriers. Using a matrix, the interactions between primary enablers, barriers and other components will be summarised.

The social scientist's analysis will be based on the constant comparative method.<sup>63</sup> The social scientist will start by closely engaging with the data collected in each maternity unit to produce a situated account of the processes, values, social interactions and meanings that appeared to be linked with the practice of employing PPH kits. Data will be compared across contexts to identify motives for their differences and similarities and will draw on concepts from the sociology of work.

To provide a comprehensive account of practice, the two researchers will combine their analyses. Attention will be paid to the overlap between the technical account of task conduct and the social influences. The output will be a set of cases that illustrate and describe the systems found in different maternity units.

## Phase II: using crowdsourcing methods to audit current practices in relation to PPH kits

### Data collection

We will invite staff from UK NHS maternity units to provide information on the design and contents of PPH kits in their units using photographs. One advantage of this method is that photographs can provide details relevant to design, such as layouts and relative sizes, that a written list of objects would not offer. By using a novel data collection technique, the study also seeks to generate interest and engagement, and thus increase participation.

An online platform called Thiscovery, which has been developed by The Healthcare Improvement Studies Institute at the University of Cambridge, will be used for data collection. First, participants will be asked to provide unit details to include unit name, type and size. Then, participants will be asked to complete four steps to (1) unpack the local PPH emergency kit, (2) photograph the design, layout and contents of the kit, (3) upload the photographs and (4) tag (label) the photographs to clarify their content.

It is important that this method is as straightforward and user-friendly as possible, placing a low time burden on participants and avoiding the need for specialised training. Thus, a user-centred design approach will be applied to develop the research activities in parallel with the platform. In practice, this means three principles from HFE will be applied:

1. An explicit understanding of the photo collection activity will be central to design.
2. The context of the work system will be considered with respect to enablers and barriers.

3. End-users will be engaged throughout an iterative development process.

To follow the first principle, a task analysis will be developed to explicitly describe the sequence of actions required, the interaction with technology and confirmatory feedback required. In addition to supporting platform development, this analysis will underpin the writing of clear user instructions, such as providing examples of good versus poor data collection practice. For the second principle, potential failure points will be assessed, and a pilot study will be conducted with the objectives of assuring both platform usability and task feasibility using the proposed online instructions. This will be conducted initially in the research institute and then in a small number of maternity sites involved in phase I. Consistent with the third principle, the ECG, which will include end-users, will be engaged to advise on the research process, review content (for example activity instructions) and provide domain-specific expertise.

### Study setting

All maternity units across the UK will be eligible for involvement using a convenience sample in which each unit self-selects inclusion. The 2019 National Maternity and Perinatal Audit<sup>64</sup> reports 288 maternity sites in the UK: 218 in England, 34 in Scotland, 25 in Wales and 11 in Northern Ireland. The majority of these comprise an obstetric unit co-located with an alongside midwifery unit, though others are free-standing midwifery or obstetric units. We will invite all maternity units in the UK to take part, with a minimum target of 58. This response level provides a reasonable degree of representativeness of item inclusion (margin of error <12%). We will track the responses as the study proceeds to ensure that we are achieving a diverse sample (with respect to unit size, type and PPH kit form) and will increase recruitment effort for under-represented unit profiles as required.

Sites will be recruited by emailing invitations to participate to lead midwives in each maternity unit. We anticipate recruiting one or two individuals per unit to undertake this activity, for example, local Practice Development Midwives. A brief project overview and participant information sheet will be sent together with a link to the Thiscovery platform. A communications campaign will be conducted, for example, through collaborations to be established with bodies such as the Royal College of Midwives, the Royal College of Obstetricians and Gynaecologists and the Obstetric Anaesthetists' Association.

### Data analysis

Initially, we will review photo quality and the completeness of photo tags, from which a summary will be compiled indicating the proportion of missing or ambiguous tags. Where there are omissions or potential errors in labelling, the ECG will be engaged to apply their knowledge to complete omissions where possible to do so. A second stage of analysis will describe and quantify the different forms of kit, the proportion of kits that are accompanied

by the PPH algorithm, the proportion of kits in which a particular item is found and the number of items in each kit.

The analysis of kit contents will establish the key ways that the contents are organised within boxes/trolleys (eg, into compartments, trays). Further analysis will draw out the relative co-occurrence of items in different stages/compartments/panels of the kit to inform a potential future design process (eg, if tape and cannulas are frequently co-located, this might be indicative of a possible benefit in doing so). Using the task analysis as a reference, judgements of how closely the grouping of items matches the task sequence and requirements will be made. With input from the ECG, examples of good versus suboptimal organisation will be produced.

It is anticipated that unit-level variables may be associated with differences in PPH kit design and contents. For example, larger units may be more likely to use trolleys and may include a greater quantity of each item in the kit. The  $\chi^2$  test will be used to test for differences in item inclusion across three predictor variables: unit size, unit type and kit form, and descriptive statistics will be used to visually represent the distribution of the quantities of kit contents.

## ETHICS AND DISSEMINATION

The first phase of this study has received ethics approval from the UK Health Research Authority and the North West Haydock Research Ethics Committee (project ID 274147).

The principal ethical concerns for this study are in phase I, where there is need to maintain the confidentiality of staff participants and assure privacy and respect for women in maternity units. We will ensure staff, women and partners are informed about the project using information sheets and posters and we will obtain verbal permission to observe. The lead fieldwork researcher has considerable experience of conducting observations in hospital settings, and the team will be sensitive to the needs and wishes of staff and women. The researchers will spend time alongside members of maternity staff and will not enter areas such as labour rooms when clinical treatments are being provided. They will only enter such areas with the permission of women and staff, and when it is appropriate to do so. Field notes will not include the names of the observed participants or any other personally identifiable information. Obstetric emergencies will not be observed directly to protect the privacy of women: the focus will be on the routines for packing, checking and preparation of emergency kits.

We will obtain informed verbal and written consent for all recorded interviews. Where recorded interviews are planned, participants will receive, at the earliest possible opportunity, written information about what the study involves, what would be requested in terms of their participation, and what precautions will be taken to ensure the anonymisation of digital recordings and transcripts. All

participants will have the opportunity to ask questions about the study directly to the researcher.

For the second phase, which does not require researcher presence on hospital sites, appropriate ethical approval will be sought if deemed necessary (current assessment suggests that it falls on the boundary of service evaluation and research according to the Health Research Authority definitions).<sup>65</sup> The subject of the photographs will be equipment, but there is a small risk that identifying information relating to individuals might inadvertently be included in an image. This risk will be minimised by providing clear instructions about the scope of task and asking participants to check whether the content is appropriate at the point of upload. Should any identifying information be photographed and uploaded, it will be redacted from the image.

On registration with Thiscovery, participants will be asked to agree to the privacy statement and the terms and conditions specific to the platform if they wish to proceed. They will be required to provide contact information: their name and their email address which will be stored on the Thiscovery database. Following submission, the research data (the photos and tags) will be disassociated from the personally identifiable data and handled separately from the database.

The academic study results will be presented at conferences, reported through the research institute's website and published in peer-reviewed journals. A communications strategy will be prepared to ensure maximum impact, including implementation of study findings. Social media will be used to generate awareness of the study's output. A brief for practitioners, written using accessible language, will be produced to include the methods, salient findings and recommendations. Stakeholder engagement (eg, with royal colleges, professional associations and policy-makers) will be used to gain support for the recommendations and facilitate uptake.

**Contributors** MD-W, TD, CW, MW and AA conceived the idea for the study. MW, AA, SM and MD-W wrote the protocol with review from TD and CW. MW wrote the paper with input from AA and MDW. All authors approved the submitted version of the paper.

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