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Study of Whole blood in Frontline Trauma (SWiFT): implementation study protocol

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ABSTRACT

Introduction Uncontrolled bleeding is a major cause of death for patients with major trauma. Current transfusion practices vary, and there is uncertainty about the optimal strategy. Whole blood (WB) transfusion, which contains all components in one bag, is considered potentially advantageous, particularly for resuscitating patients with major bleeding in the prehospital setting. It could potentially improve survival, reduce donor risk and simplify the processes of delivering blood transfusions outside hospitals. However, the evidence supporting the effectiveness and safety of WB compared with the standard separate blood component therapy is limited. A multicentre randomised controlled trial will be conducted, alongside an implementation study, to assess the efficacy, cost-effectiveness and implementation of prehospital WB transfusion in the prehospital environment. The implementation study will focus on evaluating the acceptability and integration of the intervention into clinical settings and on addressing broader contextual factors that may influence its success or failure.

Methods and analysis A type 1 effectiveness–implementation hybrid design will be employed. The implementation study will use qualitative methods, encompassing comprehensive interviews and focus groups with operational staff, patients and blood donor representatives. Staff will be purposefully selected to ensure a wide range of perspectives based on their professional background and involvement in the WB pathway. The study design includes: (1) initial assessment of current practice and processes in the WB pathway; (2) qualitative interviews with up to 40 operational staff and (3) five focus groups with staff and donor representatives. Data analysis will be guided by the theoretical lenses of the Normalisation Process Theory and the Theoretical Framework of Acceptability.

Ethics and dissemination The study was prospectively registered and approved by the South Central—Oxford C Research Ethics Committee and the Health Research Authority and Health and Care Research Wales. The results will be published in peer-reviewed journals and provided to all relevant stakeholders.

Trial registration number ISRCTN23657907; EudraCT: 2021-006876-18; IRAS Number: 300414; REC: 22/SC/0072.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Embedding this implementation study within the framework of cost-effectiveness hybrid randomised controlled trials (RCTs) offers a pragmatic approach, potentially bridging the knowledge–practice divide and addressing the challenges of applying RCTs to complex interventions.
⇒ This study augments the *Implementation Science* (*IS*) literature by introducing a method to conduct an implementation study inside a large multicentre RCT. Rooted in a pragmatic system approach and anchored in established *IS* literature, this methodology can be seamlessly adapted for other type 1 effectiveness–implementation hybrid RCTs.
⇒ This study will incorporate thorough focus groups and interviews with stakeholders from every stage of the whole blood pathway. This ensures a comprehensive data collection that encompasses all viewpoints.
⇒ Open-ended interview questions, while allow for a large range of data to be collected, require some amount of subjectivity as some topics, such as perceptions, cannot be verified objectively.
⇒ In focus groups, group dynamics can shape individual feedback. Dominant participants may overshadow others, risking groupthink and limiting diverse perspectives.

INTRODUCTION

Major trauma results in over 5400 deaths annually in the UK and even more globally, exceeding the deaths caused by HIV AIDS, tuberculosis and malaria combined.[1] Uncontrolled bleeding plays a substantial role in these fatalities, with approximately 20% happening within the first 24 hours and 40% within the first month. Blood transfusion, composed of different components such as red blood cells (RBCs), plasma and platelets, is a vital treatment in managing bleeding patients until the bleeding can be controlled in hospital. These components are derived from whole blood (WB) donations and stored separately at varying temperatures.

Observational studies in both military[2] and civilian[3 4] settings have indicated a reduction in mortality with prehospital blood transfusion; however, recent randomised controlled trials (RCTs) have shown mixed results on the benefits of prehospital blood transfusion.[5–7]

Hence, the optimal transfusion strategy in the prehospital setting remains uncertain, leading to variations in transfusion practices across the country.[8] Currently, the standard of care for most prehospital services in England do not carry blood, and the standard of care for air ambulance services (AAS) is the administration of separate blood components (RBCs and plasma), which comes with numerous logistical challenges, such as limited space in the emergency vehicles, increased weight for medical teams to carry several transfusion bags per patient and limited intravenous access to give multiple units. All these factors could delay patient transfer to hospitals, which can be detrimental to outcome. WB transfusion could overcome these challenges, and moreover, it will reduce donor exposure for patients, and potentially improve survival.

However, several systematic reviews have shown a lack of evidence that WB transfusion is superior to component therapy in improving the survival of trauma patients who are bleeding.[9–11] Moreover, WB transfusion presents its own challenges, such as higher production costs and the need for specific types of donors, making optimal utilisation of this resource crucial. An important aspect to consider is the potential for wastage of unused blood products when using WB, particularly if WB is administered to one group of patients only (such as those in the prehospital environment).[12] On the other hand, early WB transfusion could reduce the need for additional blood components on hospital arrival by controlling bleeding earlier. Therefore, assessing the clinical and cost-effectiveness of prehospital WB transfusion in a comprehensive trial before widespread National Health Service (NHS) implementation is crucial.

The Study of Whole Blood in Frontline Trauma (SWiFT) is a multicentre RCT that will determine if prehospital WB transfusion is superior to standard of care (RBCs and plasma) in reducing the proportion of participants who experience death or massive transfusion at 24 hours. Secondary outcomes of this trial include all-cause mortality, morbidity, safety, cost-effectiveness and health-related quality of life up to 90 days (more details on the SWiFT trial are in the online supplemental material).[13] The SWiFT trial plans to recruit 848 participants from at least 10 AAS across the UK. Recruitment to the trial began on 15 December 2022 and is expected to continue for 24 months, with an estimated conclusion date of 15 December 2024. It will also incorporate an implementation study designed to evaluate the acceptability and implementation of the intervention.

Implementation study

RCTs have long been hailed as the 'gold standard' for evaluating health and care interventions due to their robustness in demonstrating efficacy. However, despite their status, there are growing concerns within the research community about their limitations.[14 15] Particularly, these worries focus on issues with internal validity when broader contextual factors are not considered,[16–19] and the necessity for a tightly controlled environment to accurately assess outcomes, which may not fully reflect the complexities of real-world healthcare systems.[20]

These limitations manifest in the fact that, after 17 years, a mere 14% of healthcare research is integrated into everyday clinical practice via the traditional clinical research pipeline.[21] This disconnect has led to the development of *Implementation Science* (*IS*)[22] that studies the processes used to integrate evidence-based interventions into clinical settings by providers or organisational systems and addresses these issues directly.[22] Rather than focusing solely on intervention effects, *IS* evaluates the broader elements such as policies, procedures and contextual factors which may influence the implementation process and its success or failure.[23]

Traditionally, researchers view the journey from knowledge development to its application as a stepwise, linear progression, starting with an RCT to ascertain an intervention's efficacy under controlled conditions in specific populations, followed by 'effectiveness research' methods to evaluate interventions in less controlled environments and with more diverse populations, and finally, moving to 'implementation research' methods that investigate the best strategies to introduce the intervention into practice. Despite its systematic approach, this unidirectional progression is time-consuming and does not account for evolving clinical and policy questions, nor does it illuminate interaction effects between the intervention and its implementation strategy.[24 25]

Here is where hybrid designs[26] offer an intriguing alternative. These designs incorporate elements from both effectiveness trials and implementation trials. They consider intervention effects while simultaneously examining their implementation. This approach addresses the traditional research pipeline's common issue of substantial delays in adopting evidence-based interventions into everyday clinical practice, thereby accelerating the process and maintaining relevance.[21] By assessing effects and implementation concurrently, hybrid designs enrich our understanding of potential interactions between intervention effectiveness and its implementation approach, adding a layer of sophistication to the traditional research pipeline.[27 28]

In light of these considerations, for the SWiFT trial, we opted for a type 1 effectiveness–implementation hybrid design,[26] where assessment of clinical effectiveness and cost-effectiveness of WB will be evaluated simultaneously with the implementation of WB into routine practice. Under the proposed study design, we will scrutinise the effects of the intervention on pertinent clinical outcomes and costs, while concurrently observing and gathering data on its implementation.[26]

In this study protocol, our emphasis will be on the implementation study that will be conducted alongside the clinical and cost-effectiveness RCT.

METHODS AND ANALYSIS

Aim and objectives

This study aims to assess the acceptability and implementation of the intervention (prehospital leucocyte-depleted WB transfusion) in patients with life-threatening traumatic haemorrhage in the context of the SWiFT trial. The primary objectives are:

1. To explore the contexts in which the intervention is delivered and gauge its impacts on local (prehospital) and centralised (central blood service) systems and processes.
2. To pinpoint the mechanisms of implementation and factors that could either facilitate or impede the regular integration of the intervention into daily practice.
3. To determine the factors that affect the acceptability of the intervention, as viewed from the perspective of healthcare professionals who are involved in the entire WB pathway, from donors to recipients.
4. To inform the future adoption and implementation of the WB pathway in other contexts by identifying potential strategies for sustainable implementation.

Study design

This study is part of a type 1 effectiveness–implementation hybrid design.[26] Hybrid type 1 design is primarily an effectiveness trial of an intervention that secondarily observes and collects data on the implementation of that intervention. This study design aims to measure patient functioning or symptoms in response to a clinical intervention, while simultaneously evaluating acceptability and implementation of an intervention through qualitative, process-orientated mixed methods.[25]

This study will employ qualitative research methods, featuring in-depth interviews and focus groups with the operational staff involved in the SWiFT trial's implementation of the WB pathway, as well as patient and blood donor representatives. Qualitative research techniques have been chosen because they can provide valuable insights into the situational aspects of complex healthcare interventions.[27 29 30] As Pope and Mays[31] suggest, qualitative research 'serves as a fundamental prerequisite for rigorous quantitative research, particularly in areas that are yet to be thoroughly explored'. For these reasons, the use of qualitative methods in conjunction with RCTs to facilitate the implementation and evaluation of interventions is on the rise.[27–29]

The study design includes the following steps (figure 1):

1. Review of literature, document analysis (eg, local protocols) and informal discussions with the clinical team members to have a preliminary 'As-is' (standard of care pathway) and 'To-be' (WB pathway) process map.
2. Focus group 1 (operational staff), aimed at consolidating the 'As-is' and 'To-be' process maps and to check whether processes need adaptations across sites. The 'To-be' process map will be used to support implementation across all trial sites and the cost-effectiveness study (September, October 2023).
3. Qualitative interviews with operational staff to explore perspectives on acceptability and the impact of the implementation of the intervention in the current system and processes (September 2023 to February 2024).
4. Focus groups (n=4), three with different groups (focus groups 2–4) of operational staff involved in the WB pathway (March–May 2024) and one with patient and donor representatives (focus group 5) to review and consolidate findings emerging from the interviews

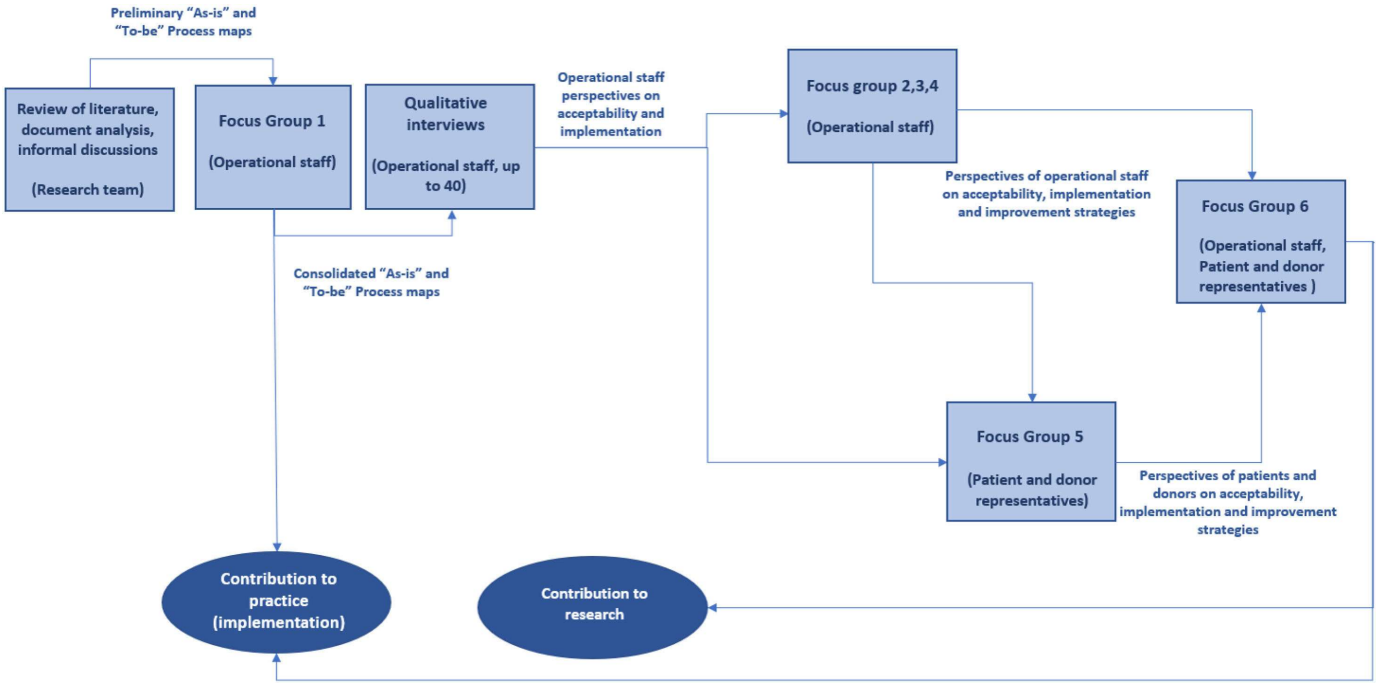

Figure 1 Study design.

and discuss strategies to improve implementation and spread in other contexts (July 2024).
5. Focus group with operational staff, patients and donor representatives (focus group 6) to consolidate and validate findings (September 2024).

This design was selected because it enables a detailed examination of perceptions regarding implementation and offers the opportunity to explore and construct meaning relevant to implementation.

The study began in August 2021 and is expected to be completed in January 2025.

Study setting

The SWiFT trial[32] involves different clinical settings starting from the point of blood donation, to manufacturing of blood units at NHS Blood and Transplant (NHSBT), and then moving to transfusion laboratories in hospitals where blood units are administered to patients; the latter will capture the processes of blood units being transported to emergency staff at the receiving AAS.

The study will involve a number of sites across England (n=10).

1. NHSBT is the main blood supplier for hospitals in England.
2. Transfusion laboratory sites (n=10) are responsible for supplying blood components in accordance with the randomisation procedure. These sites are the hospitals' transfusion laboratories which supply blood components to the participating AAS. For AAS that use freeze-dried plasma (LyoPlas), this can either be procured directly from the LyoPlas supplier by the AAS or via the transfusion laboratory.
3. Prehospital clinical teams are responsible for treating patients on scene and delivering the trial intervention prior to hospital admission. These sites will deliver a combination of RBCs and plasma as standard care for the treatment of life-threatening bleeding.
4. Receiving hospital sites (n=19) are secondary care sites where participants will be admitted following prehospital administration of the trial treatment. These sites will be designated major trauma centres, trauma units or other hospitals that receive participants from the participating AAS.

There will be some overlap between the transfusion laboratory sites and the receiving hospital sites.

Participant sampling

Study participants include operational staff involved in the WB pathway, patients and donor representatives.

A purposive sampling strategy will be used to recruit operational staff for interviews and focus groups.

Operational staff will be purposefully sampled from diverse professional backgrounds to ensure a comprehensive spectrum of perspectives and experiences across our sample. Various professionals will have different roles in the WB pathway, and their views and experiences related to its implementation will differ according to these roles. Similarly, we will recruit participants from the different sites involved in the trial. Participants from NHSBT will be recruited to ensure representation of the three manufacturing sites: Manchester, Filton and Colindale. Recruiting hospitals will be selected to ensure a diverse representation of geographical locations across England and to include both metropolitan and suburban areas. This is crucial because organisational processes, and hence implementation strategies and experiences, are likely to diverge, providing us with a wealth of data from various study settings. Operational staff will be selected based on:

1. Study sites: the hospital they work in (any of SWiFT recruiting sites).
2. Process steps: the part of the WB pathway in which they work, including transfusion laboratory, prehospital clinical team—AAS, land vehicles, receiving hospital trauma teams and NHSBT.
3. Professional group: doctors, nurses and other relevant healthcare professionals.

This approach aims to maximise the diversity of perspectives gained from interviews and focus groups.

Opportunity sampling will be used to select patient representatives who have suffered trauma in the past and are interested to help with research. Consenting donor representatives will be opportunistically sampled from interested members of the NHSBT Patient and Public Advisory Group (PPAG).

The number of participants and the sampling frame for each research activity is detailed in table 1.

Inclusion criteria to join the study are as follows:

1. *Operational staff*: healthcare professionals involved in the WB pathway at NHSBT and the sites participating in the SWiFT trial.
2. *Patient representatives*: (a) patient (of any age) who has suffered a traumatic injury; (b) consenting to be contacted to participate in the study focus groups.
3. *Donor representatives*: (1) blood donor (of any age); (2) consenting to be contacted to participate in the study focus groups.

Exclusion criteria for participating in this study are:

1. *Healthcare professionals*: (a) under 18 years old; (2) inability or refusal to provide consent for the study.
2. *Patient and donor representatives*: not consenting to be contacted to participate in the study focus groups.

Patient and public involvement

Patient representatives' perspective has been embedded in the study design and are detailed further in the relevant sections. Donor representatives will be sampled from NHSBT PPAG and patient representatives will be recruited through existing patient networks. All patient and donor representatives will be compensated according to National Institute of Health Research (NIHR) guidance for patient and public contributors.[33]

Participant recruitment

Operational staff

Individuals will be approached in person, via phone or email by the clinical trials unit who have contacts with the

Table 1 Details regarding research activities

	Participant type	Staff number	Sampling strategy
Focus group 1	Operational staff	18	6 lab staff, 6 NHSBT staff, 6 AAS staff from different professional groups.
Interviews	Operational staff	30–40	Professionals from each area of expertise (ie, 10 lab staff, 10 NHSBT, 20 prehospital setting) and different study sites.
Focus group 2	Operational staff	18–20	6–7 people from diverse recruiting hospitals working in prehospital setting (trauma team) with different professional roles.
Focus group 3	Operational staff	18–20	6–7 people from diverse recruiting hospitals working in the transfusion labs with different professional roles (eg, biomedical scientists, transfusion practitioners and haematologists).
Focus group 4	Operational staff	18–20	Healthcare staff equally distributed across the three NHSBT manufacturing sites with different professional roles (ie, from donor teams to manufacturing and logistics teams).
Focus group 5	Patient and donor representatives	10	Any age, who suffered traumatic injury (patient).
Focus group 6	Operational staff Patient and donor representatives	18 operational staff 7 patient and donor representatives	18 healthcare staff ideally representing all recruiting sites across the 3 main stages of the WB pathway with different professional roles (volunteers from focus groups 2–4 with additional participants as required). 7 patient and donor representatives (volunteers from focus group 5 and additional participants as required).

AAS, air ambulance services; NHSBT, NHS Blood and Transplant.

transfusion laboratories, staff working across NHSBT and healthcare professionals working at each of the participating sites. Other participants may be identified through snowballing. In these cases, the interviewee will be asked to contact the recommended individual to gauge interest in taking part in an interview. Interested participants will be asked to contact the research team for further information. Interview participants will be asked if they consent to be contacted to participate in focus group 2 or 3 or 4. Participants in focus group 2 or 3 or 4 will be asked if they consent to be contacted to participate in focus group 6.

Patient representatives

Patient representatives will be recruited through existing patient networks (eg, Centre for Trauma Sciences—www.c4ts.qmul.ac.uk/get-involved/get-involved, People in Research—Home—People in Research, Oxford Trauma and Emergency Care Patient and Public Involvement group—Patient and Public Involvement—Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (ox.ac.uk)) and will be contacted by the research team via email or phone. Participants in focus group 5 will be asked if they consent to be contacted to participate in focus group 6.

Donor representatives

The NHSBT PPAG will be used to seek blood donors who are happy to participate in one or both focus groups as part of this study. These contact details will be shared with the SWiFT research team. Donor representatives will be contacted by the research team via email. Participants in focus group 5 will be asked if they consent to be contacted to participate in focus group 6.

Data collection

We will decide on whether to conduct focus groups and interviews face to face or using online communication technologies/telephone based on preferences of participants and His Majesty's Government guidance at the time. Face-to-face focus groups will take place in one of the study sites.

Interviews

Up to 40 1:1 interviews with operational staff across the WB production, delivery and prehospital pathway will be conducted by one researcher. The expected duration of each interview is 45 min.

Open-ended questions will be used to explore perceptions of participants. Sampling will continue until theoretical saturation will be reached. Interview guides will be informed by the literature on acceptability and implementation.[28 34 35]

The interview guide will be reviewed by the SWiFT research team and piloted with one researcher and two healthcare professionals working across the WB pathway.

Open-ended questions will enquire about: (1) acceptability of the intervention to operational staff, (2) implementation contexts, systems and processes and (3) barriers and facilitators to implementation.

Interviews will be digitally audio recorded and transcribed verbatim by a professional transcription service (the interview guide is provided as online supplemental material).

Focus groups

The expected duration of the workshops is 2 hours, except for focus group 6, which is expected to last 3 hours

if online and a half day if in person. The focus groups will be audio recorded and transcribed by a professional transcription service. During the workshop, field notes will be collected. In case of online focus groups, collaborative online tools[36] will be used to revise and comment on process maps as well as to support discussion and share ideas. These tools allow collection and recording of notes and comments from participants and facilitator throughout the focus group.

In focus group 1, participants will be asked to provide their input about the steps, activities and resources involved in performing the 'As-is' process and about how this process should change with the intervention ('To-be' process). The use of process mapping will facilitate a more comprehensive understanding of systems and processes, given its flexibility and accessibility.[37–39] This tool's simplicity makes it equally beneficial for individuals with a limited background in quality improvement techniques.[37 38] Process maps provide a pragmatic approach to confront the complexities of health systems by dissecting processes into smaller, identifiable steps. In doing so, they allow the compilation of data and viewpoints from a multitude of sources and a diverse array of stakeholders, thereby enriching the comprehension of the process.[37 38] The process mapping exercise will be conducted in accordance with the quality criteria set out by Antonacci *et al*.[38]

Throughout the workshops, process maps will be used as a tool to prompt discussion. While the discussion in focus group 1 will be mainly focused on processes and activities, focus groups 2–4 will be mainly focused on acceptability and implementation. In these focus groups the research team will present interview findings and will prompt discussion about the implementation process, factors facilitating or hindering acceptability and implementation and potential strategies to overcome emerging challenges to implementation. In focus group 5, the research team will gather patient and donor perspectives about acceptability and implementation issues in order to understand what is important for services to be aware of if this treatment is implemented on a wider scale.

In focus group 6, the research team will present the main themes about implementation and acceptability of the intervention emerging from the interviews and previous focus groups. During the focus group, participants will be invited to discuss key findings about acceptability and implementation in the context of the SWiFT trial and key strategies for adoption and sustainable implementation of the WB pathway in other settings.

Data analysis

Transcripts will be imported into NVivo for analysis.[40] Thematic content analysis will be used to analyse and categorise qualitative data collected during the focus groups and in the interviews into recurrent and common themes.[41 42]

Interviews

A qualitative database will be developed using NVivo software[40] where a coding framework will be developed throughout an inductive and deductive process to identify themes specific to the research questions to be derived.

Following an initial stage of data familiarisation, the data will be analysed through an iterative process of coding and using the constant comparative method.[43] Two researchers will read the transcripts in full to familiarise themselves with the interviews. They will then individually open-code five transcripts before coming together to agree and define the coding structure, which will be then applied to subsequent interviews and codes refined and added. In a second stage, the two researchers will meet again to examine how the codes obtained through open coding fit with Theoretical Framework of Acceptability (TFA) (acceptability)[35] and Normalisation Process Theory (NPT)[34] core concepts (implementation). This process will continue until theoretical saturation is reached.

Acceptability is 'a multifaceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention'.[35] TFA will be used to support the analysis of findings related to acceptability as it has been successfully used in a number of studies in different healthcare settings to guide the assessment of acceptability from the perspectives of intervention deliverers and recipients, prospectively and retrospectively (including RCTs).[44 45] This theoretical framework describes acceptability as a multifaceted construct, represented by seven component constructs: (1) how an individual feels about taking part in an intervention ('Affective attitude'), (2) the perceived amount of effort that is required to participate in the intervention ('Burden'), (3) ('Perceived effectiveness'), (4) the extent to which the intervention has good fit with an individual's value system ('Ethicality'), (5) the extent to which the participant understands the intervention, and how the intervention works ('Intervention coherence'), (6) the extent to which benefits, profits, or values must be given up to engage in an intervention ('Opportunity costs') and (7) the participant's confidence that they can perform the behaviour(s) required to participate in the intervention ('Self-efficacy').[35]

NPT will be used to examine, theorise and improve how prehospital WB should be embedded in routine delivery. We considered that NPT would be a useful analytical tool because NPT is a robust and highly cited theory of implementation that helps provide awareness of the work involved in embedding and sustaining practices associated with an intervention, and thus aids understanding of what becomes normalised into everyday settings.[28 46 47] NPT is a sociological theory which explains the processes people adopt when implementing new interventions, to allow the intervention to become 'normalised' or embedded in routine practice. Four core constructs, each

with four subconstructs within them, describe generative mechanisms that facilitate normalisation and help examine: (1) the ways that people make sense of the practice ('Coherence'); (2) how they engage and participate with it ('Cognitive participation'); (3) how stakeholders come to engage with or 'enact' the practice ('Collective action') and (4) how they appraise its effects ('Reflexive monitoring').[48]

Findings will be discussed, refined and validated with the SWiFT research team. Results will serve as input for discussion in the focus groups 2–5.

Focus groups

Transcripts will be imported into NVivo and analysed using thematic analysis. Transcripts, field notes, comments and ideas shared by participants using physical or digital tools (including annotated process maps) will be analysed by researchers with the objective to refine and validate findings emerging from the interviews. Emerging ideas on strategies to address challenges to sustainable implementation and spread of the intervention to other contexts will be inductively coded using NVivo and organised in themes. One researcher will open code the transcripts and then the coding system will be discussed with another researcher and applied to the dataset. Findings will then be compared with relevant literature and discussed with the wider SWiFT trial team.

Draft case reports will be sent to participants to ask for any feedback or comments. Participants will be asked if the account is realistic and accurate and if the interpretation of the data resonates with their experiences.

DISCUSSION

This protocol delineates an implementation study embedded within a multicentre RCT, conforming to a type 1 effectiveness–implementation hybrid design.[26] Such a design facilitates concurrent evaluation of clinical and cost-effectiveness, as well as the implementation of the intervention.

This RCT will illuminate the feasibility and potential implications of using WB in a prehospital setting. In addition, it will compare the clinical and economic outcomes resulting from the WB pathway to those associated with the current practice of utilising discrete blood components.

Should the study validate the clinical impact and cost-effectiveness of the WB pathway, its broader implementation in prehospital settings could translate into improved clinical outcomes for trauma patients.[49 50] Moreover, the switch to WB could streamline logistical processes by eliminating the need to transport separate blood components. It could also potentially mitigate the risk associated with donor exposure and alleviate the economic burden on the NHS.[9–11]

The implementation study will provide valuable insights into the mechanisms and factors that underpin the seamless incorporation of the intervention into daily practice. It will achieve this by examining the factors that impact the acceptability and deployment of the intervention, as perceived by healthcare professionals engaged in the entire WB pathway, from donors to recipients. By identifying and outlining potential strategies for sustainable implementation, the study strives to guide future uptake and application of the WB pathway in a variety of NHS contexts.

The employment of a hybrid study design, which marries implementation studies with RCTs, could prove advantageous in bridging the gap between knowledge and translation.[21 51 52] It could also provide a solution to specific challenges associated with the use of RCTs in the context of complex interventions.

Notwithstanding the considerable progress made in the field of *IS* and its application in clinical research over the past decade,[26 27] the adoption of hybrid study designs in clinical research is yet to become standard practice.

The methodology proposed in this implementation study protocol uses qualitative methods such as focus groups and interviews to include a wide range of the stakeholders involved in the processes under investigation. This will allow us to gather a rich dataset on the perspectives on the implementation mechanisms and the acceptability of the new WB pathway.

Our approach adopts a system perspective, firmly rooted in well-established acceptability and implementation frameworks. By combining this systemic viewpoint with robust theories in the field of *IS* and acceptability,[34 35] we aim to garner a pragmatic understanding of how this new modus operandi will influence current practices. We will also identify potential challenges and opportunities to consider during the WB pathway implementation.

Process mapping techniques will play a critical role in our methodology, fostering a mutual comprehension of the 'work as it is' rather than the 'work as imagined'.[37 38] The creation of these process maps will occur during multidisciplinary workshops, where participants from different parts of the process and different sites can contribute their unique knowledge and experience. This collaborative effort will result in a more accurate and realistic depiction of the current practice.[37 38] These process maps will serve multiple purposes throughout the study, including acting as a visual stimulus for discussions, a foundation for process improvement analysis,and a guide for the implementation of the WB pathway.

The theoretical frameworks underpinning this study will be NPT[34] and TFA.[35]

NPT is widely used in *IS*, but its use in RCTs is still limited. Studies use NPT within RCTs largely prospectively, for example, to inform interview topic guides,[47 53 54] though have also commonly been used as a framework for data analysis.[55 56] NPT is beneficial to understanding the complex dynamics of implementation processes and identifying aspects of work that can be improved for sustainable integration into everyday practice.[28 57 58] However, reported challenges of NPT use within RCTs appear to surface when mapping data onto the constructs,

as overlap between them has been experienced.[47 59] Introducing NPT from the outset of RCT planning can provide us with the opportunity to overcome these expected challenges. Other challenges reported on the use of NPT within RCTs relate to the ability of constructs to cover specific implementation or acceptability aspects emerging from data.[28 60 61] To tackle this challenge, some studies have integrated the NPT framework with other frameworks such as the Theory of Planned Behaviour[62] and the Consolidated Framework for Implementation Research.[63]

In this study, we aim to enhance our research methodology by combining NPT and the TFA.[35] By leveraging these two frameworks, we anticipate that our approach will effectively capture the activities undertaken in the WB pathway and identify the key requirements for successful integration and acceptability of the intervention into routine practice. Nonetheless, in light of the challenges previously discussed, we acknowledge the potential need to explore additional constructs from the *IS* literature to gain further insights and enrich our data analysis.

The use of the TFA within RCTs has also been reported in some studies,[44 45] although is still limited. Reported challenges related to the use of this framework, similarly to NPT, involve themes emerging from the data that are not covered by the seven constructs of the theory. For example, one study found the theme of trust to be crucial to the acceptability of the trial and therefore adapted the TFA to include 'Trust' as an added eighth construct to the theory.[45]

Employing a type 1 effectiveness–implementation hybrid design affords a holistic understanding of the intervention's clinical outcomes, cost metrics, and practical application in the real world.[26] This paper expands the *IS* literature by proposing a method for conducting an implementation study within a large multicentre RCT, founded on a pragmatic system approach and firmly grounded in solid *IS* literature. This methodology could be easily adapted to other type 1 effectiveness–implementation hybrid design RCTs.

The research steered by this protocol aims to enrich the *IS* literature, offering additional evidence on how system approaches and *IS* theories can illuminate the acceptability and effects engendered by the implementation of the intervention within existing systems and processes in the context of RCTs. Furthermore, this study holds implications for practice, as the insights derived from the implementation study will provide practical recommendations for effectively deploying the WB pathways in other NHS sites, should the trial results support its use.

ETHICS AND DISSEMINATION

The SWiFT trial was prospectively registered and approved by the South Central—Oxford C Research Ethics Committee and the Health Research Authority and Health and Care Research Wales prior to the commencement of this implementation study (REC reference 22/SC/0072; IRAS 300414). The results will be published in peer-reviewed journals and provided to all relevant stakeholders.

Consent to enter the implementation study will be sought from each participant after a full explanation has been given, an information sheet will be offered and time allowed for consideration. All study participants will be sent a copy of the study information sheet via email prior to the interview or focus group date. We will ensure that the study information sheet for potential participants has the complete description of the research study including detail on the participants' right to anonymity, confidentiality of the data, right to withdraw and the benefits of participation. The email will explain that participation in the interviews and focus groups is voluntary. Prior to the interview and focus group each interviewee will sign an informed consent form. Operational staff participating in the interviews will receive a £10 honorarium (Amazon voucher) to compensate them for their time, while patient and donor representatives will be paid according to NIHR guidance for patient and public contributors.[33] As the majority of participants will be NHS staff members, it is anticipated that all participants will have sufficient understanding of English to read and understand the participant information sheet and consent form. Patient and donor representatives will be asked if they are capable of communicating in English (both verbal and written) as part of their consent process and will be invited in the focus groups only if they meet this requirement.

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Contributors GA conceived the implementation study protocol and drafted the paper. LG and JS supervised the team and are the chief investigators of the SWiFT trial. All authors (GA, AW, LG and JS) provided editorial and intellectual input, contributed to subsequent revisions and approved the final manuscript.

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