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Prehospital whole blood in the SWiFT hybrid type 1 trial: a qualitative implementation study guided by Normalization Process Theory

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Abstract

Background

Prehospital transfusion of whole blood is a promising strategy for treating traumatic haemorrhage, but its introduction into civilian health systems requires coordinated change across blood manufacturing, hospital laboratory and prehospital services. The Study of Whole Blood in Frontline Trauma (SWiFT) was the first UK randomised trial comparing prehospital whole blood with component therapy (red blood cells and plasma), and included an embedded implementation study. The trial found that prehospital whole blood was not superior to component therapy on the primary clinical outcome, with a comparable safety profile. We explored how whole blood was introduced and operationalised across the service pathway, guided by Normalization Process Theory.

Methods

A qualitative implementation study (August 2021–January 2025) was embedded within the trial's type 1 hybrid effectiveness–implementation design. Data were collected across the pathway, from NHS Blood and Transplant manufacturing sites and hospital transfusion laboratories to ten air ambulance services, using observations, process mapping, focus groups and semi-structured interviews. Twenty-five interviews and three focus groups were conducted with prehospital clinicians, biomedical scientists, transfusion practitioners, haematologists and blood service staff. Data were analysed thematically (inductive–deductive) and mapped onto the four Normalization Process Theory constructs: coherence, cognitive participation, collective action and reflexive monitoring.

Results

Participants rapidly differentiated whole blood from component therapy and viewed it as clinically logical and procedurally clear. Strong cognitive participation was evident, with early champions, high staff buy-in and a shared commitment to evidence generation. Collective action involved significant but manageable adaptations to standard operating procedures, logistics, stock management and documentation, such as double-checking, revised packing and QR-coded randomisation cards. Reflexive monitoring was supported by frequent governance meetings, routine auditing of 'blood-on-board' boxes and iterative problem-solving around errors, wastage and stock distribution. Persistent challenges included O Rh-negative supply constraints, staff workload and concerns about trial-specific complexity versus future routine practice.

Conclusions

Prehospital whole blood was perceived as acceptable and operationally feasible across a multi-organisational service pathway, with strong engagement and adaptive reconfiguration of work. The analysis identified mechanisms supporting implementation, and supply, governance and sustainability issues that health services must address before wider adoption.

Trial registration:

ISRCTN23657907. Registered 7 December 2022.

Background

Major trauma is a leading cause of preventable mortality globally, accounting for over 5 million deaths annually [1]. Uncontrolled haemorrhage is the leading cause of potentially preventable death following injury, implicated in up to 30–40% and occurring predominantly within the first hours after injury [2]. In the UK, trauma accounts for over 5,400 deaths annually, with haemorrhage representing a disproportionate share of early, preventable deaths [3]. Current prehospital transfusion strategies typically rely on separate blood components, red blood cells (RBCs) and plasma, each requiring distinct storage, transport, and administration processes [4]. Prehospital platelet transfusion is not possible due to the need for constant agitation. These operational constraints pose challenges for air ambulance services (AAS) and prehospital teams, contributing to delays in treatment and variability in service provision across regions [4].

Whole blood (WB) transfusion, which contains RBCs, plasma, and platelets in a single bag, has re-emerged as a potentially superior component logistically for use in prehospital resuscitation [5, 6]. Observational studies have suggested potential associations between early WB use and improved outcomes, although findings are heterogeneous and randomised evidence has been limited [7, 8]. Additional advantages include reduced donor exposure, more physiologically balanced resuscitation and logistical benefits of administering combined components versus separate components [9].

The Study of Whole Blood in Frontline Trauma (SWiFT) is the first multicentre randomised controlled trial (RCT) in England to compare prehospital WB transfusion with the current standard of care (i.e. RBCs and plasma) [10, 11]. Embedded within SWiFT is a parallel implementation study, recognising WB transfusion not merely as a clinical intervention but as a complex organisational innovation spanning multiple systems: NHS Blood and Transplant (NHSBT), transfusion laboratories, AAS, and receiving hospitals [12]. Understanding how supply chains, documentation, stock management, and governance interact is crucial for evaluating feasibility and informing national scale-up.

Although RCTs remain central to evaluating clinical effectiveness, they may not fully capture the contextual, behavioural, and organisational processes that shape the implementation and adoption of complex interventions in routine practice [13, 14]. This is particularly salient for complex interventions, where clinical outcomes are intimately linked to implementation quality [15, 16]. Traditional linear

models of evidence translation, moving from efficacy to effectiveness to implementation, are increasingly recognised as too slow and insufficiently responsive to system complexity [15, 16]. This has driven the development of implementation science, which seeks to understand how interventions are adopted, integrated, and sustained in routine practice [17]. Hybrid effectiveness–implementation designs, such as that used in SWiFT, allow simultaneous assessment of clinical outcomes and implementation processes, potentially accelerating translation into practice [10, 12, 17–19].

SWiFT has recently reported its primary findings: prehospital transfusion of up to two units of whole blood was not superior to standard component therapy in reducing the composite outcome of death or massive transfusion within 24 hours (relative risk 1.02, 95% confidence interval 0.80–1.31; p = 0.84), with no safety concerns identified [11]. A parallel within-trial economic evaluation (unpublished data) suggests that prehospital WB may be cost-effective compared with standard care from an NHS and personal social services perspective, despite the absence of a clinical superiority signal. However, whether an intervention of this kind can be adopted by health services depends not only on clinical and economic evidence but also on the organisational work required to deliver it across blood services, hospital laboratories and prehospital providers. The aim of this study was therefore to explore how prehospital WB transfusion was understood, operationalised and sustained across this multi-organisational service pathway during the SWiFT trial. By analysing the data through the lens of Normalization Process Theory (NPT), this study identifies mechanisms that influenced the acceptability, integration, and sustainability of WB during the trial. The findings aim to inform future policy, pathway redesign, and decisions regarding potential national adoption of prehospital WB transfusion.

Methods

Study design

The study protocol has been published previously [12]. The implementation component followed a qualitative design aligned with a Type 1 effectiveness–implementation hybrid model, which allows simultaneous assessment of clinical outcomes and the processes needed to support real-world adoption [12]. WB requires coordinated implementation across manufacturing, laboratory and prehospital settings, making a multi-organisational implementation study appropriate.

Setting

The study was conducted across multiple settings, integral to the delivery of WB in routine practice, including NHSBT manufacturing sites, hospitals (i.e. transfusion laboratories) and prehospital services (i.e. ten air ambulance services (AAS) that took part in the trial).

Theoretical framework

To analyse the system-level processes underpinning the implementation of prehospital WB, this study applied NPT. NPT explains how new practices become embedded in routine clinical work through four generative constructs: (i) Coherence: how individuals make sense of the new practice; (ii) Cognitive participation: how stakeholders engage and commit to it; (iii) Collective action: how the intervention is operationalised and enacted; (iv) Reflexive monitoring: how the practice is appraised and adapted over time [19–22]. NPT has been widely used in complex interventions, including digital health and pathway redesigns, making it well-suited to WB transfusion, where adoption spans manufacturing through to patient delivery [19, 23, 24].

Participants and recruitment

Participants were purposively sampled to maximise variation in roles, organisational settings, and geographical distribution. Staff involved in any part of the WB pathway, including paramedics, physicians, nurses, biomedical scientists, transfusion practitioners, haematologists, and logistics personnel, were eligible to participate. Inclusion criteria required participants to be ≥ 18 years old, involved in the pathway, and able to provide informed consent. Participants were approached by the research team via email. Recruitment continued until theoretical saturation was reached [12].

Data collection

The study was conducted between August 2021 and January 2025 using observations, one-to-one online interviews, and online focus groups. Following ethical review, we began with observations in one hospital transfusion laboratory and one NHSBT manufacturing site to understand existing processes; field notes were taken during these observations and used to inform the development of initial process maps, which were subsequently validated and used as a basis for discussion in two focus groups: the first in September 2023 (8 participants, 4 research team, 3 laboratory, and 1 prehospital staff) and the second in October 2023 (11 participants: 5 research team and 6 NHSBT staff). Each focus group lasted approximately 2 hours and explored collaborative processes, supporting the mapping of both ‘as-is’ and ‘to-be’ workflows. Insights generated during these sessions provided additional contextual understanding and informed the development of the interview guide.

A total of 25 one-to-one semi-structured interviews (approximately 45 minutes each) were then conducted: 7 with laboratory staff, 8 with NHSBT staff, and 10 with prehospital staff (Table 1). Interviews explored participants’ perceptions of WB, anticipated and experienced operational burden, interactions with existing workflows, resource implications, documentation challenges, safety concerns, and perceived sustainability. The interview guide was informed by acceptability and implementation literature, including NPT [19, 20], ensuring coverage of both experiential and system-level dimensions of implementation, and was further shaped by insights from observations and focus groups. The guide was reviewed by the SWiFT research team and piloted with one researcher and two healthcare professionals working across the WB pathway (Additional file 1).

Table 1
Interview participants

Transcript Code	Operational Process	Profession
PH_1	Prehospital	Consultant in emergency and prehospital care
PH_2	Prehospital	Consultant in prehospital care, Clinical Lead for major haemorrhage
PH_3	Prehospital	Specialist practitioner in critical care
PH_4	Prehospital	Doctor, clinical academic fellow
PH_5	Prehospital	Doctor in critical care and prehospital care
PH_6	Prehospital	Doctor in critical care and prehospital care
PH_7	Prehospital	Critical care paramedic
PH_8	Prehospital	Consultant in emergency medicine and prehospital care
PH_9	Prehospital	Consultant in prehospital care
PH_10	Prehospital	Critical care doctor
BT_1	NHSBT	Consultant haematologist
BT_2	NHSBT	Supply Chain Planning Manager
BT_3	NHSBT	Doctor, clinical research fellow
BT_4	NHSBT	Consultant clinical scientist
BT_5	NHSBT	Senior healthcare technical officer
BT_6	NHSBT	Consultant clinical scientist
BT_7	NHSBT	Senior healthcare technical officer
BT_8	NHSBT	Supervisor in manufacturing
L_1	Hospital lab	Advanced biomedical scientist
L_2	Hospital lab	Transfusion laboratory manager
L_3	Hospital lab	Operational lab manager
L_4	Hospital lab	Laboratory manager for blood transfusion
L_5	Hospital lab	Biomedical scientist in blood transfusion
L_6	Hospital lab	Senior biomedical scientist
L_7	Hospital lab	Senior biomedical scientist in transfusion

A final focus group was conducted in November 2024 with transfusion laboratory staff, NHSBT teams, and AAS clinicians (20 participants: 3 research team, 5 NHSBT, 9 laboratory, and 3 prehospital staff), to validate and refine preliminary findings. Throughout the workshops, process maps have been used as a tool to prompt discussion [25, 26]. Importantly, data collection was completed before the primary clinical results of the SWiFT trial were available. Therefore, participants' accounts reflected their experiences of implementing the intervention during trial delivery and were not influenced by knowledge of the trial's effectiveness findings.

Data analysis

All interviews and focus groups were audio-recorded, transcribed verbatim, and anonymised. Field notes documenting non-verbal cues, contextual observations, and operational nuances were incorporated into the dataset. Data were analysed using an inductive–deductive thematic approach [27, 28]. Two researchers independently coded an initial subset of transcripts to develop a preliminary coding framework, which was iteratively refined through team discussion. NVivo 12 (QSR International Pty Ltd., Melbourne, Australia) was used to manage the dataset, support coding consistency, and facilitate cross-case comparison. An inductive coding phase allowed themes to emerge from the dataset, followed by a deductive phase in which themes were mapped onto the four core constructs of NPT: coherence, cognitive participation, collective action, and reflexive monitoring [20].

[AUTHORS TO CONFIRM – BMC requires any use of large language models to be documented in the Methods. If none was used, delete this note; otherwise state, e.g.: "A large language model (name, version) was used for language editing of the manuscript; the authors reviewed and take full responsibility for the content."]

Rigour and reporting

Rigour was enhanced through multiple validation strategies. Process maps and preliminary themes were presented during the focus groups for respondent validation (‘member checking’), enabling participants to assess the credibility of interpretations and refine emergent insights. Draft thematic summaries were shared with individuals who volunteered for follow-up feedback, strengthening interpretive consistency. An audit trail documenting analytic decisions was maintained within NVivo, supporting transparency and trustworthiness [29].

The study is reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) [29], and the intervention is described using the Template for Intervention Description and Replication (TIDieR) checklist [30] (Additional file 2).

Ethical considerations

Ethical approval

was granted by the South Central – Oxford C Research Ethics Committee (REC 22/SC/0072) and the Health Research Authority (Integrated Research Application System [IRAS] number 300414). All participants provided written informed consent. Participants received vouchers as compensation for their time.

Results

The findings are organised using NPT's four constructs (coherence, cognitive participation, collective action, and reflexive monitoring) reflecting stakeholder experiences across the WB pathway. Table 2 summarises the main themes emerging within each construct, illustrating these with selected participant quotes.

Coherence

Differentiation

The analysis of the Coherence sub-construct of differentiation highlighted both advantages and challenges in how WB is distinguished from components therapy. WB, as a treatment option, was largely seen as an improvement in terms of clinical efficiency. Many participants (12 of 25: 4 NHSBT, 3 laboratory, 5 prehospital) appreciated its simplified transfusion process, particularly in laboratory and prehospital settings, where the need to administer fewer bags (two instead of four) was seen as a significant benefit. This reduction in complexity was welcomed, as it allowed for faster, more streamlined care, with one participant noting that it made blood transfusions easier and less prone to error in high-pressure environments.

However, the differentiation of WB from standard blood components raised some logistical and clinical concerns. Wastage, in part due to the shorter shelf life of WB and restricted use for the prehospital setting only as part of SWiFT trial, was frequently (14 of the 25 interview participants, predominantly laboratory and NHSBT/blood-service staff rather than prehospital clinicians) mentioned as a barrier to its widespread adoption, as well as concerns around stock management. Additionally, the differentiation of WB also required some modification to existing processes, including an adapted way to train staff and adjustments to Standard Operating Procedures (SOPs) as part of trial delivery, such as adding a QR code to the randomisation cards to aid in the required paperwork and alerting the research team of the patient.

Communal specification

The communal specification sub-construct emphasised the need for clear communication and coordination across various teams involved in the SWiFT trial, including laboratories, blood services, and prehospital units. Participants (15 of 25: 2 NHSBT, 4 laboratory, 9 prehospital) highlighted the importance of having a clear ordering system and proper documentation to prevent logistical challenges such as incorrect randomisations or incomplete forms. While adjustments to existing processes were

required, including updates to randomisation protocols and tracking systems, one laboratory participant specifically described a learning curve, noting that as the trial progressed, there was increased familiarity with the procedures, improving efficiency. However, concerns around resource management remained, particularly in balancing supply and demand for WB. Participants suggested that, if WB were adopted more widely in routine practice, greater integration and coordination could be achieved.

Individual specification

The individual specification sub-construct of Coherence revealed a focus on the personal responsibility and self-monitoring involved in the SWiFT trial. Participants (9 of 25: 3 NHSBT, 3 laboratory, 3 prehospital) noted the importance of tracking and verifying processes to ensure the correct handling and delivery of WB, often taking extra steps to audit and follow up on usage and waste. While some participants (12 of 25: 3 NHSBT, 4 laboratory, 5 prehospital) expressed concerns about the adequacy of stock levels and the timeliness of deliveries, others found value in the personalised oversight they provided in ensuring that the protocol was followed and issues were addressed promptly. These same participants (see tracking and auditing, above) were involved in routine checks, including ensuring proper documentation and data tracking, which contributed to a sense of ownership and responsibility for the success of the trial. However, participants recognised that much of the additional workload was related to trial-specific procedures. They suggested that, if simplified single-bag transfusion pathways were implemented in routine practice, the personal burden could decrease as workflows became more streamlined.

Internalisation

Participants identified factors influencing potential integration of WB into routine practice. Firstly, they emphasised the need to integrate WB into regular workflows, suggesting that it should be treated as a sustainable, long-term practice rather than a trial-based intervention. They identified the importance of improving ordering systems, with a call for more intuitive technological interfaces between NHSBT and hospitals to streamline stock management and alleviate cumbersome processes. While the trial initially introduced complexity, participants noted that adapting to new protocols and additional paperwork had become more normalised within their workflows over time. Building on the wastage concerns noted above, participants advocated for extending its use beyond prehospital settings to ensure no product goes unused, particularly for patients requiring major haemorrhage protocols in hospitals. However, there remained a level of scepticism regarding the broader adoption of WB, with participants stressing the need for robust evidence on its clinical benefits to justify its continued use and integration into routine care.

Cognitive participation

Initiation

The initiation of the SWiFT trial was marked by well-established key individuals driving the intervention forward, particularly with requests from air ambulance staff for WB use (16 of 25 participants: 4 NHSBT,

4 laboratory, 8 prehospital, referred to this early push), driving the process years before the trial officially began. This foundation laid the groundwork for the structured approach at initiation, with early stakeholder engagement ensuring necessary approvals were secured before launch. Adequate training of staff was a critical aspect of the early phase, as effective communication and awareness about the trial were essential for smooth implementation.

Enrolment

The enrolment process was strongly aligned with the belief that the intervention should become part of routine practice. All participants (25 of 25) reported feeling adequately trained and stressed the importance of training to ensure staff were fully familiar with trial processes, highlighting the need for seamless integration into their daily workflows. There was also a clear recognition, among 15 of 25 participants (6 NHSBT, 2 laboratory, 7 prehospital), of the need to raise awareness among staff and the public to encourage greater donor participation and patient recruitment, which reflected a collective value of the trial's importance. Efficient patient consent and data collection processes were seen as essential for successful enrolment, with participants agreeing that these steps were necessary to include patients in the trial. Organisational involvement from all three operational staffing groups demonstrated a commitment to the trial and showed that WB can be effectively incorporated into their care protocols.

Legitimation

The legitimacy of the SWiFT trial is strongly supported by participants as they recognise its crucial role in answering critical questions regarding the use of WB in trauma care. A number of participants (7 of 25: 5 NHSBT, 2 prehospital) expressed that the trial is essential not only for improving patient outcomes but also for ensuring that blood products are used effectively and without waste. There was a strong sense of buy-in from both colleagues and organisations, with many viewing the trial as aligning with broader goals of enhancing patient care and the opportunity to save more lives. Additionally, the international interest in the trial’s findings adds to its credibility and importance. The commitment to evidence-based practices was another key factor in the trial’s legitimacy. Participants emphasised the need for robust data to guide future clinical decisions and solidify the role of WB in trauma care, reinforcing the intervention's value within the medical community.

Activation

In regard to the activation sub-construct of NPT, participants’ continued support for the intervention is evident in their active engagement throughout the trial. Comprehensive training and clear guidance at the trial's start were pivotal in ensuring that staff felt prepared to handle the new procedures, contributing to sustained support for the intervention. While there was initial confusion about the new processes (raised by 6 of 25 participants: 1 NHSBT, 3 laboratory, 2 prehospital), one laboratory participant described how hands-on experience with test boxes had clarified operations for them. The integration of new procedures with existing workflows was largely smooth, with minimal disruption to regular operations, which helped maintain ongoing support for the intervention. Looking ahead,

participants expressed optimism that if the trial demonstrates significant benefits, they would like to see WB adopted more widely for use in-hospital, namely in emergency departments, thereby influencing future clinical practices and further reinforcing support for its continued use.

Collective action

Interactional workability

The introduction of the SWiFT trial led to an indication of increased stress among all staff as they adjusted to new processes and navigated ongoing staff shortages, initially exacerbated by COVID-19. Despite this, many participants (16 of 25: 7 NHSBT, 5 laboratory, 4 prehospital) noted the benefits of WB, such as simplifying logistics for air ambulances by reducing the number of components to manage during emergencies, which ultimately made the process more efficient. Strong collaboration and communication pathways facilitated task performance, although occasional lapses in following procedures and documentation errors were reported by 16 of 25 participants (3 NHSBT, 5 laboratory, 8 prehospital). Staff expressed confidence in their colleagues' abilities; many attributed this to the training provided and their familiarity with existing procedures, which together helped the trial integrate with minimal disruption. Additionally, participants noted that WB reduced wastage compared with thawed plasma (standard care) and enabled quicker patient care in prehospital settings, ultimately enhancing the overall efficiency of care delivery and supporting continued task performance.

Relational integration

The implementation of the trial has highlighted the importance of maintaining trust among teams, a theme raised explicitly by 7 of 25 participants (1 NHSBT, 2 laboratory, 4 prehospital). Collaborative planning has been crucial, particularly with the introduction of standing orders, which have allowed for more predictable coordination of blood supplies and usage across teams. This change has led to improved communication and trust between staff in prehospital, lab and NHSBT. Team communication has been further enhanced, for some (4 of 25: 1 NHSBT, 3 prehospital), by regular discussions and updates via platforms such as WhatsApp, ensuring smooth coordination around patient recruitment, paperwork and the logistics of supply. The integration of WB into established workflows has been perceived as minimal disruption, supporting staff in adapting quickly while maintaining trust in each other's competence and commitment to the trial's goals. This relational integration has been key to ensuring the trial runs smoothly and that patient care remains at the forefront of the process.

Skill-set workability

The SWiFT trial highlighted the need for role-specific training, especially for laboratory staff, to ensure correct processing and randomisation, with one laboratory participant describing a two-person check introduced during packing to minimise errors. This focused training approach was integral in ensuring that personnel involved in these critical tasks felt confident in their ability to successfully complete their work. The complexity of the SOPs was reduced by aiding the detailed written instructions with practical

demonstrations, making it easier for staff to understand and apply the necessary procedures. Continuous training was also emphasised to ensure new staff quickly became proficient in the trial procedures, though some staff noted that newer staff were trained on the procedures, but not necessarily the ‘why’ behind them. Logistically, the trial ultimately simplified certain aspects of administration for prehospital teams, which appear to have improved efficiency compared to the standard of care.

Contextual integration

The integration of the SWiFT trial into existing systems was shaped by several contextual factors, including challenges posed by post-COVID conditions, referenced explicitly by 2 of 25 participants, though broader staffing-shortage pressures (see Interactional Workability) were more widely reported. The pandemic exacerbated staffing shortages and blood supply issues, which increased workload and stress among staff. Effective supply management, particularly for Group O Rh-negative blood, became critical to prevent wastage and ensure that clinical demands were met, emphasising the need for consistent stock levels. Despite these challenges, the trial's procedures largely aligned with pre-existing protocols, requiring only minor refinements to accommodate trial-specific protocols, which facilitated smoother integration into regular operations. However, logistical concerns, such as managing the shelf life of WB, remained prominent. To ensure successful integration, continuous training and support were identified as essential for staff to adapt to WB usage and maintain adherence to the new protocols, ensuring that the intervention was adequately supported within the host organisation.

Reflexive monitoring

Systematisation

The systematisation of the trial has involved efforts to track and monitor compliance with established protocols, but participants have expressed that access to concrete data on the trial's effectiveness is naturally limited due to it being ongoing. While there are tracking mechanisms in place for patient enrolment and documentation, participants have indicated that they do not yet have access to definitive results or clear data on the trial's outcomes. There was a strong sense of anticipation, with many participants (12 of 25: 5 NHSBT, 1 laboratory, 6 prehospital) expressing hope that the trial would generate robust evidence to support improvements in the care of patients with traumatic haemorrhage. For many, whole blood represented a promising approach through which these improvements might be achieved. However, the lack of comprehensive data on the effects of the intervention means that staff cannot fully assess its impact yet. Despite this, the systematic approach to tracking procedures and ongoing data collection, particularly around wastage and stock management, provides participants with valuable operational insights, even if the trial’s clinical outcomes have not yet been determined. As the trial progresses, there is an expectation that more information will become available, helping to shape future decisions around the intervention.

Communal appraisal

Operational staff of the trial collectively assess the intervention as worthwhile, but logistical challenges due to the nature of a multi-centre RCT and stock management remain prominent considerations. The balance between the need to manufacture sufficient stock while minimising wastage is compounded by the challenge of ensuring a reliable supply of O Rh-negative blood donors. However, there is a shared commitment to overcoming these challenges, with participants acknowledging the importance of whole blood in improving patient outcomes. To address these obstacles, awareness and education efforts are emphasised, with calls to raise public and staff awareness about blood donation and its potential benefits. A minority of participants (2 of 25) pointed to governance meetings and monitoring systems as essential in tracking incidents, fostering a sense of shared responsibility and collaboration. Staff also believe that expanding the use of WB beyond prehospital settings, particularly for major haemorrhage cases in hospital units such as emergency and obstetric departments, would be a further step in building the case for wider adoption.

Individual appraisal

The interviews revealed that staff individually assessed the trial as worthwhile, though some noted individuals took personal responsibility for monitoring and auditing the trial's processes, ensuring that any discrepancies in usage or documentation were addressed promptly. Participants (11 of 25: 3 NHSBT, 1 laboratory, 7 prehospital) emphasised the importance of enrolling patients appropriately, adhering to trial protocols, and ensuring proper data collection. This active engagement in the trial was viewed as essential for evaluating the effectiveness of WB use, even though there is a call for more conclusive results before fully endorsing its widespread adoption.

Reconfiguration

Staff have made modifications to their work in response to their experience during the trial, adapting both operational procedures and resource management strategies to improve the intervention’s effectiveness. One key modification was the adjustment of SOPs to address the complexities of processing whole blood. For instance, to improve clarity and efficiency, staff shifted to more practical demonstrations rather than relying solely on the detailed written instructions in the SOPs. A notable example involved adapting how units were handled, with staff shifting from performing each step for a single unit at a time to preparing multiple units simultaneously, a modification that simplified the workflow and reduced confusion. The need for increased coordination and problem-solving due to the trial's demands led to the development of new processes, such as placing the randomisation card on the box more securely after an earlier incident where it fell off. Further, the addition of a QR code aided in streamlining the documentation process. This change was implemented to ensure quicker data collection and improve efficiency in tracking and monitoring.

Table 2
Normalization Process Theory constructs, implementation themes and representative quotes

NPT Construct	Theme	Representative Quote	Source
Coherence	Procedural Clarity	"Honestly, of all the clinical trials I've been involved with, this one is about the least different between standard care and intervention arm."	PH_1
	Understanding Context	"We now know that the factors involved in coagulation are legion over what we thought 40 years ago."	PH_10
Cognitive Participation	Initial Willingness	"Everyone wanted to be involved, the teams wanted to see if it would really make a difference."	PH_2
	Building Competence	"10 out of 10 to be honest, because they are very confident... They understand the theory part really well."	L_6
Collective Action	Adapting Processes	"We implemented a second check during packing: that really reduced the number of errors."	L_3
	Managing Supply	"We originally were doing hand-to-mouth stock management... We've changed our process now to have some stock within each manufacturing site."	BT_2
	Logistical Execution	"It's easier to give. I open a box and fist bump that I found the whole blood because it's going to be two bags, not four."	PH_7
Reflexive Monitoring	Formal Governance	"We have a senior and quality meeting every fortnight... Is everything going well? Have we had problems?"	L_4
	Continuous Monitoring	"Every day, I check the Blood on Board boxes and audit them... ensuring the card stays in place."	L_1
	Problem-Solving	"We realised we didn't use the randomisation numbers in numerical order... So we soon learned we had to put them into numerical order."	L_7

Discussion

This implementation study, embedded within the SWiFT trial, provides insights into the enablers and challenges of introducing prehospital WB transfusion in the UK [12]. Guided by NPT [19], the findings highlight both the operational feasibility and the contextual barriers to normalisation, offering direction for policy, practice, and future research on complex transfusion innovations [31].

Coherence around WB's simplifying logic was tempered by the concrete work of local adaptation – revised SOPs, QR-coded cards and self-monitoring – underlining that sense-making is inseparable from system-level change. Cognitive participation was sustained by clinical champions and perceived legitimacy despite added workload, reflecting NPT's emphasis on enrolment, legitimation, and activation

[31]. Collective action depended on manageable but real adaptations to logistics and stock management, tested throughout by pressures largely outside staff control: post-COVID staffing, O Rh-negative supply, and geographic variation in supply chains [4, 32]. Reflexive monitoring, through both formal governance and informal daily practice, allowed local adaptation even before unblinded trial results were available.

Analysis through the NPT lens showed that WB's apparent procedural simplicity concealed substantial ongoing relational and organisational work, the central mechanism by which a seemingly straightforward product change was embedded into routine prehospital practice.

These findings are consistent with international experience of prehospital whole blood. Observational and implementation studies in military and civilian settings have reported that whole blood programmes are logistically feasible, can reduce donor exposure, and may be associated with improved survival and haemodynamic stability in patients with traumatic haemorrhage [9, 33]. US civilian emergency medical services programmes and Scandinavian experiences, including the Norwegian helicopter emergency medical services whole blood programme, describe similar advantages in simplifying transfusion logistics and minimising the number of units and connections required during prehospital resuscitation [34]. At the same time, randomised trials and high-quality evaluations underscore that demonstrating a clear mortality and cost-effectiveness benefit over component therapy remains challenging, owing to issues such as sample size, heterogeneity of injury patterns, and the complexity of prehospital systems [33, 35]. The RePHILL trial found no statistically significant difference in the composite primary outcome between prehospital blood products and crystalloid in adults with haemorrhagic shock, highlighting the need to interpret implementation successes alongside nuanced clinical results [35]. Similarly, the PAMPer and COMBAT trials produced discordant results on the utility of prehospital plasma, with a combined post-hoc analysis suggesting a survival benefit when transport times exceeded 20 minutes [36–38]. The SWiFT trial itself found that prehospital WB was not superior to standard component therapy in reducing the composite outcome of death or massive transfusion at 24 hours (relative risk 1.02, 95% confidence interval 0.80–1.31) [11]. Although the comparable safety profile and the logistical advantages identified in this implementation study remain valid, these findings underscore the importance of rigorous implementation evidence in informing adoption decisions. Notably, a parallel within-trial economic evaluation (unpublished data) suggests that WB may be cost-effective compared with standard care, a benefit also reflected in interview accounts describing combined components as operationally and economically advantageous; considering cost-effectiveness alongside clinical and implementation evidence is therefore essential to a complete picture of WB's value.

Our use of NPT to analyse SWiFT implementation extends existing implementation science work in transfusion medicine and complex interventions more broadly. NPT has previously been applied to digital health technologies, integrated care pathways, and other service-level innovations, demonstrating that successful normalisation depends on a balanced alignment of coherence, cognitive participation, collective action, and reflexive monitoring [31]. The present study shows how trial-specific demands, especially extensive documentation and strict eligibility criteria can intensify the work required for

collective action and reflexive monitoring, a pattern observed in other hybrid effectiveness-implementation designs for complex interventions [17]. In contrast with the relatively centralised logistics of military systems, our findings highlight the challenges of implementing WB across a distributed civilian network, where regional variation in geography, donor pools, and service configuration has implications for equity and sustainability [32, 34].

Implications for practice and policy

These findings have important implications for prehospital and transfusion services considering the introduction or wider adoption of WB. More broadly, several implementation challenges identified in this study, including workflow integration, training, governance, and supply-chain coordination, may also be relevant when introducing other simplified single-bag transfusion products, although this was not directly examined in the present study. First, the strong coherence and cognitive participation observed suggest that frontline staff in laboratories, blood services, and prehospital teams are receptive to WB as a concept and perceive it as aligned with current paradigms of damage control resuscitation. This provides a foundation for scalability if operational arrangements do not impose disproportionate additional burdens. Second, from a practical standpoint, integrating WB into major haemorrhage protocols may simplify prehospital workflows, reduce the number of components managed, and potentially shorten the time to effective resuscitation in severely injured patients [33, 35]. Third, policy development must explicitly address stock management and geographical equity. Participants' concerns regarding O Rh-negative supply, wastage, and inter-site variation echo international reports identifying donor recruitment, stock management, and product distribution as critical determinants of sustainability [4, 32, 34]. Strategies such as regional stock hubs, standing orders, flexibility in WB use for in-hospital major haemorrhage scenarios, and real-time wastage monitoring could help maximise utilisation and justify the additional supply chain complexity [32, 34]. Other service-level strategies to improve blood availability may also warrant consideration depending on local service configuration. Fourth, the emphasis on communication and relational integration suggests that investment in shared information systems, including electronic ordering, integrated tracking, and routine feedback dashboards, would support coordination and governance, provided these tools are designed to reduce rather than increase administrative burden.

Finally, training and workforce development will be central to successful scale-up. Our findings suggest that role-specific, continuous training that explains not only procedures but also the rationale for WB is necessary to maintain competence and engagement, particularly in the context of staff turnover and service pressures [31]. Ensuring that laboratory staff, prehospital clinicians, and NHSBT personnel have protected time and institutional support to participate in such training will be crucial if the intervention is to normalise as routine practice rather than remaining confined to the trial period [17, 31].

Strengths and limitations

A key strength of this study is its embedding within a multicentre randomised trial, using a Type 1 hybrid effectiveness-implementation design, which allows the contextualisation of implementation processes

alongside clinical and economic outcomes [17]. Purposive sampling across stakeholder groups and multiple sites, combined with in-depth qualitative methods and NPT, enhances the richness and transferability of the findings [12]. Methodological rigour was further supported by iterative coding, team-based analysis, member-checking, and the use of qualitative data management software to maintain an audit trail and facilitate cross-case comparison [12].

However, several limitations must be acknowledged. The trial context means that some barriers and facilitators, particularly those relating to documentation, governance, and restrictions to prehospital-only use, may be specific to the research phase and may not fully reflect routine service conditions after trial completion [12]. Participants were all engaged in the trial and may therefore be more motivated or positively disposed towards WB than staff who did not participate, raising the possibility of selection bias [12]. In addition, the study did not include the perspectives of patients, family members, or in-hospital recipients, who might reveal additional considerations regarding acceptability, consent, and downstream care coordination [35]. Finally, as qualitative research, this study is not designed to quantify the causal effects of specific implementation strategies on clinical outcomes. Such judgements must be made in conjunction with the primary clinical and health economic findings from SWiFT [11].

Future research

Future research should move beyond the trial context to evaluate the feasibility, implementation, and sustainability of prehospital WB in routine practice [17]. Pragmatic implementation studies, including further hybrid effectiveness-implementation designs, are needed to examine how relaxation of trial-specific constraints, such as strict eligibility criteria, intensive data collection, and prehospital-only indications, affects operational performance, wastage, and clinical outcomes in real-world settings [17]. Comparative research could explore different stock management models, including broader in-hospital indications for WB in major haemorrhage, to understand how best to balance product availability, donor resources, and costs [32, 34]. Longitudinal studies would be valuable to track how coherence, participation, and reflexive monitoring evolve once WB is embedded as standard of care, particularly in relation to workforce changes, evolving transfusion guidelines, and technological developments in blood banking [31]. Equity and economics-focused evaluations should examine how WB programmes can be designed to maintain access across urban and rural areas, minimising geographical disparities in trauma care [32, 34]. Finally, comparative international implementation work, drawing on military, North American, European, and Australian experiences, could contribute to context-sensitive but generalisable guidance for scaling up prehospital WB safely and sustainably [33, 34].

Conclusions

The SWiFT trial has demonstrated that prehospital whole blood is operationally feasible and safe, with a comparable clinical profile to standard component therapy [11]. Cost, alongside clinical and implementation evidence, will also be an important driver of any future decision to implement WB more

widely. A parallel within-trial health economic evaluation (unpublished data) suggests that WB may be cost-effective compared with standard care. The implementation findings reported here identify the organisational mechanisms that enabled delivery across a complex multi-sector pathway and highlight the supply, governance, and sustainability conditions required for any future adoption at scale. Together, clinical, economic and implementation evidence from SWiFT provide a comprehensive foundation to inform evidence-based, equitable decisions about the role of whole blood in UK prehospital trauma care.

Abbreviations

AAS
Air ambulance service(s)
COREQ
Consolidated Criteria for Reporting Qualitative Research
CTIMP
Clinical Trial of an Investigational Medicinal Product
GCP
Good Clinical Practice
IRAS
Integrated Research Application System
NHS
National Health Service
NHSBT
NHS Blood and Transplant
NPT
Normalization Process Theory
QR
Quick response (code)
RBC
Red blood cell(s)
RCT
Randomised controlled trial
REC
Research Ethics Committee
SOP
Standard operating procedure
SWiFT
Study of Whole Blood in Frontline Trauma
TIDieR
Template for Intervention Description and Replication
WB

Whole blood

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki, the principles of Good Clinical Practice (GCP) and all applicable UK regulatory requirements. The SWiFT trial, a Clinical Trial of an Investigational Medicinal Product (CTIMP), and its embedded implementation study received approval from the South Central – Oxford C Research Ethics Committee (Ref: 22/SC/0072), the Health Research Authority (IRAS number 300414), the Confidentiality Advisory Group (Ref: 22/CAG/0050) and the research and development departments of all participating sites. All staff who took part in the interviews, focus groups and observations for the implementation study provided written informed consent before participation.

Consent for publication

Not applicable. No individually identifiable data, images or personal information are included in this manuscript. Participant quotes are presented in anonymised form using transcript codes.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available due to the terms of ethical approval and participant confidentiality, but are available from the corresponding author on reasonable request and subject to appropriate data sharing agreements.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

GA: conceptualisation, methodology, project administration, supervision, investigation, data collection, writing – original draft, writing – review and editing. AW: data collection, formal analysis. LG and JS: conceptualisation, funding acquisition, supervision, investigation, writing – review and editing. EB, CR, TW and MH: writing – review and editing. All authors read and approved the final manuscript.

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