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Clinical paper

A comparative analysis of current out-of-hospital transfusion protocols to expert recommendations

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Abstract

Aim: This study aimed to compare current out-of-hospital transfusion (OHT) protocols in Canadian civilian critical care transport organizations (CCTO) to expert recommendations and explore the variability and potential benefits of standardizing OHT practices across Canada.

Methods: A comprehensive cross-sectional study was conducted, encompassing all seven Canadian CCTOs that provide OHT. The study assessed adherence to expert recommendations and examined specific aspects of the transfusion process, such as indications for transfusion and cessation criteria.

Results: The study found an 89% adherence to expert recommendations for OHT among Canadian CCTOs. It highlighted a strong alignment between current practices and recommendations, possibly attributed to collaborative frameworks like the CAN-PATT network. However, notable variability and ambiguity were observed in transfusion indications and cessation criteria. The study also emphasized the potential benefits of standardizing OHT practices, such as improved policy formulation, better interpretation of emerging literature, and evaluation of OHT efficacy.

Conclusion: This cross-sectional study assessed how Canadian CCTOs implement OHT practices compared to expert-recommended practices. The findings underscore the importance of structured protocols in trauma management. Given the consistency in OHT protocol adoption and the comprehensive approach across CCTOs, there's a solid foundation for managing trauma patients in prehospital and transport settings across Canada. As OHT practices continue to evolve, sustained efforts are vital to refine, adapt, and elevate patient care standards in trauma management.

Keywords: Prehospital, Critical Care Transport, Trauma, Hemorrhage, Transfusion

Introduction

Hemorrhagic shock is one of the leading causes of preventable death worldwide, resulting in an estimated 1.9 million deaths annually worldwide.[1] Trauma is the leading cause of hemorrhagic shock and the foremost cause of death in people under the age of 44, resulting in an estimated 1.5 million deaths per year.[1–3] Prompt and effective management of hemorrhagic shock is critical in preventing trauma-related deaths.[1] The essential components of this management involve controlling the bleeding and restoring the patient's intravascular volume, oxygen-carrying and clotting capacity.[1] Aggressive hemorrhage control and resuscitation must be performed early since this approach has been shown to improve outcomes and reduce mortality rates in trauma patients.[1] Accordingly, early resuscitation involving out-of-hospital transfusion (OHT) is emerging in prehospital and transport settings.[4–7] OHT refers to the transfusion of whole blood, blood components such as red blood cells (RBCs) and plasma, or blood products such as fibrinogen and prothrombin complex concentrate (PCC) in the prehospital and transport setting.[6,7]

Canada's vast geography and isolated communities present unique obstacles to the deployment of OHT programs.[8,9] Many remote areas lack immediate access to healthcare facilities, and the long-distance transportation of blood products introduces logistical complexities that can delay critical interventions.[8,9] Thus, a multidisciplinary approach involving healthcare providers, logistics experts, and community stakeholders is necessary to ensure the safe and effective delivery of blood products in these settings.[8,9] Fur-

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thermore, protocols are necessary for standardized, efficient and safe care in critical care transport organizations (CCTO).[10,11] Recent efforts to harmonize OHT practices led to a national consensus document.[17] Engaging experts across various medical fields, this Delphi study yielded 39 expert consensus statements and nine quality metrics, offering a blueprint for standardized OHT protocols.[17] Given that these recommendations are new, it remains uncertain whether adherence to these practices will be observed among Canadian CCTOs. This study aims to bridge this gap by contrasting current OHT protocols in CCTOs against these expert guidelines, thereby identifying the extent of standardization in OHT practices across Canada.

Methods

Ethical approval was obtained from the Unity Health Toronto Research Ethics Board (REB 23-087). This paper is reported according to the Consensus-based checklist for reporting of survey studies (CROSS)[12] checklist (Supplementary Appendix 1).

Study design

We conducted a cross-sectional survey to examine current OHT protocols among Canadian civilian CCTOs and how they compare to recently published expert consensus statements.[11] Each of the statement and quality metric were translated into a survey question. A preliminary version of the survey was piloted with a select group comprising two transport and transfusion medicine specialists. This pilot test instigated further refinement, including more precise phrasing of items, consolidation of some questions, and introduction of novel survey items. The final survey was comprised of 39 expert consensus statements and nine quality metrics.[11] It covered general oversight, clinical governance, and specifics about storage, transportation, and initiating transfusion, among other domains related to OHT protocols (Supplementary Appendix 2). The survey was delivered using an online survey tool (JotForm, https://www.jotform.com/). Purposive sampling was used to select medical directors, managers, and providers from CCTOs. Data was collected between June 1 and August 15, 2023, and analyzed using Microsoft Excel 365 (Version 16.75.2, Microsoft Corporation Inc, Redmond, Washington). Results were summarized descriptively.

Setting and participants

In Canada, each province has its unique approach to critical care transport, including varying governance structures and team compositions. These teams may comprise physicians from various specialties, registered nurses, and specialized paramedics. To standardize and evaluate the effectiveness of OHT practices across the country, the Canadian Prehospital and Transport Transfusion (CAN-PATT) network was established.[13] This network involves clinicians and researchers from all over Canada and serves as a central hub for optimizing OHT procedures.[13]

Recruitment

The list of contacts for the survey was sourced from the CAN-PATT network, which was assumed to provide a comprehensive overview of active Critical Care Transport Organizations (CCTOs) involved in OHT in Canada. To ensure complete coverage, we confirmed the list of CCTOs through additional databases and consultations with experts in the field. Snowballing techniques were also applied; initial survey recipients were encouraged to forward the invitation to participate to other qualified CCTOs. We could track which CCTOs responded, ensuring no duplication in the responses. Each CCTO was limited to a single response to maintain the integrity of the survey data. The survey participation was tracked diligently to ensure one response per CCTO. A comprehensive list of all CCTOs that have an OHT program in Canada contacted for this study is provided in Fig. 1 for reference.

Fig. 1. Canadian civilian critical care transport organizations with out-of-hospital transfusion programs.

Results

The six civilian CCTOs within the CAN-PATT network were contacted, and the response rate was 100%. One additional CCTO that

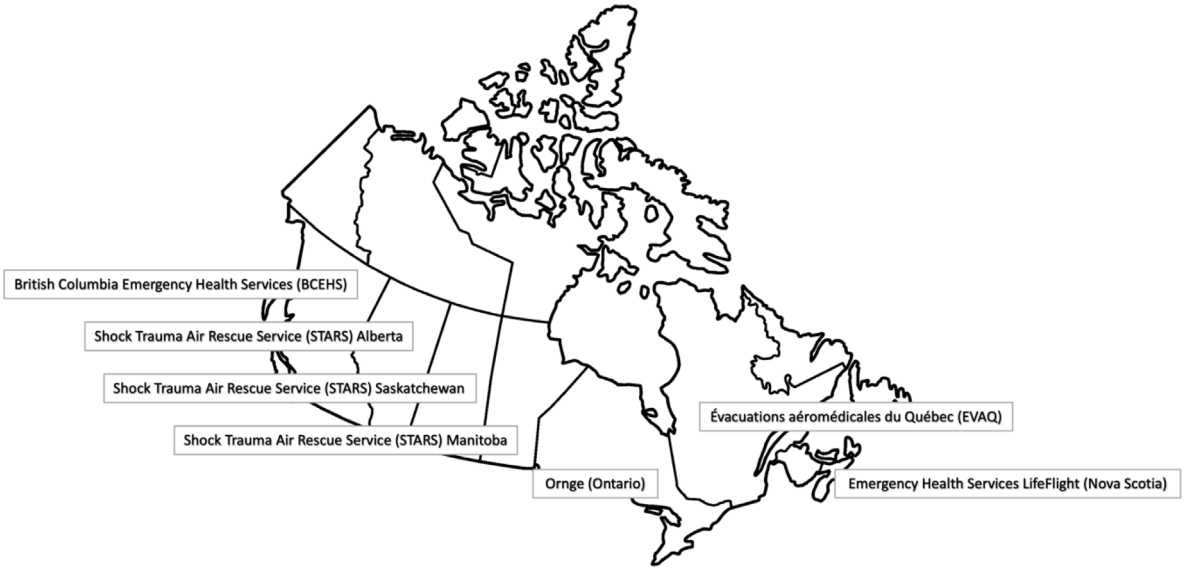

Fig. 1 – Critical care transport organizations (CCTOs) with Out-of-Hospital (OHT) programs across Canada.

has an OHT program was identified in the province of Quebec. There is one additional CCTO in Canada, however, it does not currently have an OHT program. In total 7 out of 8 provincial CCTOs within Canada currently have an OHT program. The following seven Canadian CCTOs participated in this study: British Columbia Emergency Health Services (BCEHS), Shock Trauma Air Rescue Service (STARS) Alberta, STARS Saskatchewan, STARS Manitoba, Ornge (Ontario), Évacuations aéromédicales du Québec (EVAQ), and Emergency Health Services LifeFlight (Nova Scotia). There was no missing data.

Out of 39 expert consensus statements and nine quality metrics across the seven CCTOs, there was an overall 89% adherence to expert-recommended guidelines. The range of adherence to OHT guidelines varied between 75% and 98% among individual CCTOs. The findings of this study are presented in Tables 1–5.

General oversight and clinical governance

Almost all of the seven responding CCTOs (6/7) have established OHT protocols developed by multidisciplinary teams in alignment with expert-recommended guidelines (Table 1). Five of seven CCTOs have incorporated damage-control resuscitation elements in their OHT protocols. A smaller number, 4/7, specify in their protocols the types and amounts of blood components and products that can be stored and transported. It's worth noting that each CCTO has designated leads for handling OHT-related issues, and nearly all (6/7) have a specific individual or committee focused on quality assurance for OHT. Adverse events are fully documented across all CCTOs, but only 3/7 regularly track quality metrics.

Storage and transport of blood components and products

All CCTOs adhere to national and regional standards for storing blood components and products (Table 2). Six of the seven CCTOs closely inspect and monitor their storage containers at defined times. Additionally, all CCTOs ensure that their prehospital providers receive training on the safe storage and handling of blood components and products.

Initiation of OHT

Most CCTOs (5/7) utilize clinical and biochemical indicators, such as systolic blood pressure and hemoglobin levels, for initiating OHT protocols (Table 3). However, only 2/7 of the organizations gather pre-transfusion blood samples for ABO and Rh typing when feasible.

Types of blood components and products

Most CCTOs (6/7) transport red blood cells, but notably, none carry platelets, freeze-dried plasma, or whole blood (Table 4). A minority (2/7) of CCTOs store and transport 2000 IU of PCC and 4 g of fibrinogen concentrate as an alternative to thawed plasma. Among the CCTOs, one commented that they are waiting for more safety data on the combination of fibrinogen and PCC as an alternative to thawed plasma for prehospital use. As a result, two CCTOs carry only PCC.

Table 1 – Survey Results Out-of-Hospital Transfusions (OHT) Protocols: General oversight and clinical governance.

General oversight and clinical governance.	Yes (*n*)	Yes (%)
In your CCTO, is there a protocol to guide out-of-hospital transfusion (OHT)?	6	85.7
Was the out-of-hospital transfusion (OHT) protocol developed by a multidisciplinary team, approved by the participating transfusion service, and complied with best practices and local and national transfusion guidelines?	6	85.7
Does the OHT protocol incorporate principles of damage-control resuscitation, including appropriate treatment of ongoing hemorrhage and careful selection of a receiving hospital that can provide appropriate definite hemorrhage control?	5	71.4
Does the OHT protocol reflect the types and amounts of blood components and products which can be stored and transported by the CCTO, as well as additional components and products which might be available from sending facilities?	4	57.1
Is the OHT protocol reviewed at specified intervals when the CCTO adopts new relevant products or procedures or if new practice-changing evidence emerges?	6	85.7
Does the OHT protocol include there should be specific guidance provided for selected patient populations?	5	71.4
Does your CCTO have named lead(s) and contact person(s) for any issues related to OHT?	7	100.0
Does your CCTO have a designated individual (for example, the named lead for OHT, see previous question) or committee that reviews OHT practices for quality assurance?	6	85.7
In addition to the minimal regional and national training requirements for competence in blood product transfusion, are your prehospital care providers trained explicitly for blood transfusion in the prehospital or transport medicine setting?	7	100.0
Are all clinical or administrative adverse events, errors or near-misses documented and reported through the CCTO's incident report system?	7	100.0
Does the documentation and reporting of OHT clinical or administrative adverse events, errors or near-misses through the CCTO's incident report system trigger a notification of the named lead(s) of the CCTO and the participating transfusion service?	6	85.7
Are the quality metrics mentioned in the previous questions tracked on all OHTs, and are the data reviewed quarterly at the CCTO's medical advisory committee with representation from the participating transfusion service?	3	42.9
If the patient (or a substitute decision maker) cannot consent to OHT, is this documented in the CCTO's patient's records?	6	85.7
If patient consent can be obtained, does the documentation explain the risks and alternatives to OHT?	3	42.9
Does your critical care transport organization comply with all Health Canada Blood Regulations, applicable Canadian Standards Association, and provincial standards which govern OHT?	7	100.0

Table 2 – Survey Results Out-of-Hospital Transfusions (OHT) Protocols: Storage and transport of blood components and products.

Storage and transport of blood components and products	Yes (*n*)	Yes (%)
Are blood components and products stored in validated storage containers per the participating transfusion service's national and regional accreditation standards?	7	100.0
Are containers closely inspected/monitored for any compromise or defects at defined times (e.g. start and end of shift, before initiating OHTs, on return to the participating transfusion service)?	6	85.7
If a temperature monitoring device is included in the storage container, are they inspected for temperature range violations before initiating OHT?	5	71.4
Have all prehospital providers handling blood components and products received training regarding the safe storage and handling of the containers and the procedures for receiving and returning blood components and products from/to the transfusion service?	7	100.0

Table 3 – Survey Results Out-of-Hospital Transfusions (OHT) Protocols: Initiation of out-of-hospital transfusion.

Initiation of out-of-hospital transfusion.	Yes (*n*)	Yes (%)
Does the OHT protocol include clinical (e.g. systolic blood pressure) and biochemical indicators (e.g. hemoglobin)?	5	71.4
Which of the following indicators are included in the OHT protocol?		
Systolic blood pressure <90 mmHg	5	71.4
Heart rate >110/min	4	57.1
Clinical signs of end-organ dysfunction	4	57.1
Lactate >4 mmol/L	3	42.9
Hb <90 g/L	4	57.1
Base excess <−6	2	28.6
In addition to acute hemorrhagic shock, can the OHT be initiated in other cases where a transport physician considers the benefits to outweigh the risks?	6	85.7
Can the OHT be commenced without physician authorization within the boundaries of a clearly defined medical directive, or if the anticipated delay would result in significant harm to the patient (e.g. severe hemodynamic compromise)?	4	57.1
Is the indication for commencing OHT documented in the patient's records?	7	100.0
If feasible, are pre-transfusion blood samples obtained by the prehospital provider to be used by the hospital transfusion service for ABO and Rh investigations?	2	28.6

Delivery and monitoring of OHT

Almost all CCTOs (6/7) provide a Standard Operating Procedure (SOP) to their prehospital providers to administer and monitor OHT (Table 4). Every CCTO employs commercial, portable warming devices for transfusion and has measures to prevent hypothermia in patients.

Indications for and use of transfusion adjuncts

In all responding CCTOs, Tranexamic Acid is administered for hemorrhagic shock due to trauma (Table 5). Most CCTOs (4/7) administer PCC empirically for adult patients requiring OHT due to hemorrhage and taking warfarin or a direct Xa inhibitor (e.g. rivaroxaban, apixaban, edoxaban).

Resuscitation targets to halt ongoing transfusion

Most CCTOs (6/7) reassess OHT when specific systolic blood pressure targets are met in acute traumatic hemorrhagic shock (Table 5). Additional physiological metrics, such as heart rate and lactate levels, are considered by most (5/7) to guide the rate and volume of ongoing OHT, especially during longer transfers.

Discussion

This study provides a comprehensive comparison of the current OHT protocols utilized by Canadian CCTOs to recently published expert recommendations on out-of-hospital transfusion practices.[11] All seven Canadian CCTOs that provide OHT were included in the study. It revealed three pivotal findings: the prevalent adherence to expert recommendations in OHT protocols; notable variability and ambiguity in certain aspects of the transfusion process, specifically transfusion indications and cessation criteria; and the potential benefits of a standardized OHT practice in terms of policy formulation, literature interpretation, and exploration of efficacy.

Adherence to expert recommendations

This study found 89% adherence to all expert-recommended practices for OHT in Canadian CCTOs. Given these expert recommendations were just released within a year of this study, our results likely capture what the current OHT practices were prior to CCTO consideration of these new expert recommendations. It is evident from the study that at this baseline there is significant alignment between the

Table 4 – Survey Results Out-of-Hospital Transfusions (OHT) Protocols: Types, delivery, and monitoring of blood components and products.

Types of blood components and products	Yes (*n*)	Yes (%)
What type of blood components does your CCTO carry?		
Red blood cells (RBCs)	6	85.7
Fresh frozen plasma (FFP)	1	14.3
Platelets (PLT)	0	0
Freeze-dried plasma (FDP)	0	0
Whole blood (WB)	0	0
Does your CCTO store and transport 2000 IU of Prothrombin complex concentrate (PCC) and 4 g of fibrinogen concentrate as an alternative to thawed plasma?	2	28.6
Can additional blood components and products, such as larger volumes of RBCs or thawed plasma, platelets, or specific clotting factor concentrates, be requested from the sending healthcare facility as required?	7	100.0
Delivery and monitoring of out-of-hospital transfusion	**Yes (*n*)**	**Yes (%)**
Do prehospital providers have access to a standard operating procedure (SOP) which includes the indication, administration, and monitoring of OHT and the management of adverse reactions?	6	85.7
Are RBCs and plasma given through a commercial, portable, and approved warming device?	7	100.0
Do all patients receiving OHTs have a temperature measured within 30 minutes of provider assessment and at least every 30 minutes (or continuously where available) until arrival at the receiving hospital?	6	85.7
Do all patients receive interventions to prevent hypothermia and achieve normothermia (−36 °C)?	7	100.0
Are point-of-care hemoglobin, lactate and/or base excess utilized to guide OHT?	7	100.0
Do monitoring and clinical management of transfusion reactions follow the same standards as in-hospital blood transfusions?	7	100.0

Table 5 – Survey Results Out-of-Hospital Transfusions (OHT) Protocols: Transfusion adjuncts and resuscitation targets.

Indications for and use of transfusion adjuncts.	Yes (*n*)	Yes (%)
Is Tranexamic Acid (TXA) given as soon as possible with any OHT for hemorrhagic shock due to trauma within 3 hrs?	7	100.0
Is TXA given as soon as possible with any OHT for hypovolemic shock due to post-partum hemorrhage?	6	85.7
Is calcium gluconate or calcium chloride prompted by the OHT protocols at defined intervals (e.g. after two units and then every four units thereafter)?	7	100.0
Is prothrombin complex concentrate (PCC) 2000 IU given empirically for adult patients requiring OHT due to hemorrhage and taking warfarin or a direct Xa inhibitor (e.g. rivaroxaban, apixaban, edoxaban)?	4	57.1
Resuscitation targets to halt ongoing transfusion	**Yes (n)**	**Yes (%)**
Is OHT re-evaluated if the following systolic blood pressure (SBP) has been achieved in acute traumatic hemorrhagic shock: SBP −90 mmHg if blunt trauma; SBP −110 if suspected or confirmed traumatic brain injury; SBP ≥ 80 in penetrating trauma	6	85.7
For longer transfers, particularly inter-facility transfers, or patients where active bleeding has stopped, which of the following factors are used to guide the amount and speed of OHT, in addition to systolic blood pressure:		
Heart rate	5	71.4
Lactate	4	57.1
Hemoglobin	5	71.4
Base excess	4	57.1
Signs of organ dysfunction (e.g. urine output, signs of cardiac ischemia, level of consciousness)	5	71.4

current OHT practices in Canada and expert consensus. This alignment is encouraging, especially considering the complexities associated with trauma management and the variability of practices globally. One potential reason behind such robust adherence could be the existence of collaborative frameworks like the CAN-PATT network or the relatively few CCTOs providing OHT in Canada.[13] Canada has a publicly funded healthcare system administered at a provincial level. This provincial oversight model is embedded into CCTOs across Canada, so each province has its own CCTO. Provincially based critical care transport teams, rather than hospital-based, significantly reduce the number of organizations providing OHT across Canada. A national working group like CAN-PATT might

serve as a model for other countries seeking to standardize their prehospital care practices.

Variability in transfusion indications

The study's examination of OHT practices revealed pronounced variability in criteria for initiating and terminating OHT, mirroring the findings of previous studies.[11] Specifically, two critical challenges in consensus emerged: the timing of OHT initiation in out-of-hospital settings and the choice of blood components or products. While numerous predictive tools exist for massive transfusions in trauma situations within emergency departments, their validity is questionable in prehospital environments, especially for non-traumatic major hemorrhages.[14] Vopelius-Feldt et al. emphasized the need for individualized protocols, accounting for diverse patient demographics and Canada's unique geographical constraints.[11] Additionally, choosing appropriate blood components posed challenges. Discrepancies between transfusion experts on the risk of Rh-D sensitization and clinicians led to a leaning towards recommending O Rh-D negative RBCs for CCTOs.[11] Compounding the issue, the limited plasma availability contrasted with the clinical preference for stocks providing clotting factors and volume. This led to considerations of alternatives like Prothrombin Complex Concentrate and Fibrinogen. Drawing from these insights, it's clear that the nuanced challenges in defining OHT indications and selecting appropriate blood components aren't limited to our study but are reflected globally. The shared challenges observed in both studies underscore the pressing need for a continuous and dynamic dialogue among stakeholders, encompassing patient-facing clinicians and transfusion specialists, to refine and enhance OHT protocols.

Opportunities of standardizing OHT practices

Although direct evidence supporting the life-saving potential of prehospital transfusion remains elusive, the standardization of OHT practices carries intrinsic value. Expert-recommended guidelines may provide opportunities for organizations to be better equipped to formulate new OHT policies, interpret emerging literature, and evaluate the efficacy of OHT in real-world settings. Standardization may allow for consistent care delivery across different CCTOs, something that is especially important with recent shortage of Type O blood red blood cells. For example, national guidelines can support a strategy on how best to utilize OHT in the setting of an acute blood shortage. Additionally, the emphasis on standardized training and governance is crucial, particularly in CCTOs that do not have a physician on board. A well-defined governance structure and comprehensive training programs ensure that medical staff are adequately prepared to administer OHT, thereby minimizing risks and optimizing patient care.

Strengths and limitations

The strength of this study lies in its comprehensive approach, capturing the practices of all seven Canadian CCTOs that provide OHT. However, it is essential to acknowledge its limitations. This study was performed exclusively within Canadian OHT practices, and thus, both the relevance of expert recommendations and adherence to these needs to be elucidated in other countries. Due to the survey-based methodology, reliance on self-reporting could introduce biases or inaccuracies. Moreover, while the study provides a thorough comparison, it does not delve deep into the direct efficacy of these protocols on patient outcomes.

Conclusion

This cross-sectional study assessed how Canadian CCTOs implement OHT practices compared to expert-recommended practices. The findings underscore the importance of structured protocols in trauma management. Given the consistency in OHT protocol adoption and the comprehensive approach across CCTOs, there's a solid foundation for managing trauma patients in prehospital and transport settings across Canada. As OHT practices continue to evolve, sustained efforts are vital to refine, adapt, and elevate patient care standards in trauma management.

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CRediT authorship contribution statement

Pierre-Marc Dion: Conceptualization, Methodology, Investigation, Data curation, Writing – original draft. **Adam Greene:** Conceptualization, Data curation, Writing – review & editing. **Andrew Beckett:** Conceptualization, Methodology, Writing – review & editing. **Johannes von Vopelius-Feldt:** Writing – review & editing. **Brodie Nolan:** Supervision, Conceptualization, Methodology, Investigation, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary material to this article can be found online at https://doi.org/10.1016/j.resplu.2023.100498.

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