

The Colorado Whole Blood Coalition (CWBC)

Structure, Governance & Operations Proposal: April, 2023

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Mission:

₩hat to we do; whom do we serve; how do we serve them]

To establish and maintain a collaborative structure that will facilitate and allow for the implementation of safe, effective, and interconnected whole blood programs throughout the state of Colorado.

Vison:

[future-looking--what do we want to become?]

To make whole blood readily available to every patient in Colorado who can benefit from its use

Purpose:

- Develop a structure that provides every RETAC an opportunity to participate in the development of a
 prehospital whole blood program within the state of Colorado
- Establish clear goals and objectives for an aligned vision among the many and varied organizations needed to realize a successful program
- Establish clear lines of communication among the participating and interested organizations
- Develop consistent protocols and processes that may be adopted by local implementation groups seeking to bring whole blood to their local agency or facility
- Support the local implementation of a program to recruit donors for the whole blood program and generate an adequate supply of whole blood to meet the needs of patients who will benefit
- Request and recommend use of funds though participating organizations, including participating RETACs, to support CWBC work as a whole
- Develop coordinated efforts to provide quality assurance and data collection to guide and support whole blood program development
- Support local implementation groups through sharing of knowledge, development of protocols and processes, and mentoring of new startups
- Provide ongoing direction, vision, and support to locally implemented whole blood programs around the state as the system matures

Overview

The Colorado Whole Blood Coalition (CWBC) is a group of professionals and partnering organizations interested in working together to bring whole blood to patients in the state of Colorado in both prehospital settings and in-hospital settings. We believe that a successful program requires significant collaboration between many involved parties. As such, we have sought to form a coalition to guide the development of a program framework that can be used to implement local programs throughout the state in a sustainable and safe manner. All participation in the Colorado Whole Blood Coalition is strictly voluntary. We promote a consistent and collaborative approach to whole blood programs, which we believe will in turn serve to make whole blood more widely available to patients across Colorado.

Colorado Whole Blood Coalition Governance Structure

1) Definition of Roles

- a) The CWBC voting body will consist of eleven RETAC Representatives and an eight-member Advisory Committee. This group will meet monthly to oversee collaborative work within the CWBC.
- b) The role of the RETAC Representative
 - Each RETAC representative will be identified by the RETAC who wishes to participate in the CWBC. The identification process will be up to the RETAC. Once identified, the RETAC director will present the identified representative to the CWBC as their approved representative.
 - ii) RETAC representatives will be responsible for communication between the CWBC and their local RETAC. Any local implementation work groups will collaborate with the RETAC representative.
 - iii) RETAC representatives will be voting members of the CWBC.
 - iv) A RETAC may opt out but may contact the CWBC at a later date to join the coalition.
- c) Advisory Committee
 - i) General Description: The CWBC Advisory Committee with coordinate the development of a prehospital whole blood program in the state of Colorado. This committee will consist of individuals who will represent each key functional groups needed for a successful whole blood program. The committee will make recommendations to the whole coalition as well as oversee standing committees, ad-hoc committees, and work groups.
 - ii) Nominations to the advisory committee will be accepted for a designated period each year and the RETACs will be notified when the nomination window is open.
 - iii) Expected participation by committee members: [To be outlined by the CWBC once established]
 - iv) Removal of advisory committee members: [To be outlined by the CWBC once established]
 - v) EMS Medical Director: One medical director overseeing an EMS agency in Colorado with a current whole blood program or actively working toward implementation of a whole blood program.
 - vi) Ground EMS leader: One EMS ground agency leader who oversees work within an agency with a current whole blood program or actively working toward implementation of a whole blood program.
 - vii) Trauma Medical Director (TMD) (Rotation Center): One trauma surgeon from a center that serves, or will serve, as a rotation center for whole blood within the program.
 - viii)Trauma Program Leader (Rotation Center): One trauma program manager or director who oversees a trauma program that serves, or will serve, as a rotation center for whole blood within the program.
 - ix) Blood Bank/Supplier: One representative who oversees or has influence over operations within a group responsible for blood product collection, manufacturing, and distribution and provides service to an identified rotation center within the program.
 - x) Blood Bank Rep (Rotation Center): One lab medical director or operational manager/director from an identified rotation center within the program.
 - xi) Rural Facility Rep (Rotation Site): One representative from a lower volume rural Level III or Level IV trauma center currently serving, or with intent to serve, as a rotation site for whole blood within the program. This person may be a hospital, ED, or trauma program leader, but should be able to speak to hospital operations related to blood supply and utilization within small rural facilities.
 - xii) Air Medical Program Leader: One leader from an air medical program operating within the state of Colorado. This may be a medical director or operational leader within the program.
 - xiii) Advisory Committee Officers

- (1) The advisory committee will elect from among the advisory committee members officers to facilitate internal operations and communication. There will be each of the following offices which with annual nominations and elections held by all voting members of the CWBC. Outgoing officers will remain in an advisory role to the incoming officers for an additional 6 months beyond their 1-year term.
 - (a) Chair: Leads meetings, collaborates with standing committee and ad-hoc committees
 - (b) Co-chair:
 - (c) Secretary: Sends meeting invites, posts minutes, sends group communications within the CWBC and to any established distribution lists external to the CWBC.

d) Specialty Liaisons

- i) Specialty liaisons are non-voting members who will participate in the advisory committee. These liaisons will be appointed by their parent organization and brought forward to the CWBC either at the request of their organization or at the request of CWBC. The purpose of this role is to facilitate communication and input from the many and varied organizations who are interested in understanding and facilitating the work being done but may not have a specific organizational role in the work of developing, implementing, and administering the whole blood program. Some
- ii) CDPHE Representative
- iii) STAC Representative
- iv) MCI/Healthcare Coalitions
- v) Others as approved by advisory committee

2) Description of Standing Committees

- a) Each standing committee will identify a chair who will be responsible for coordinating work, running any meetings, and reporting and communication back to the CWBC voting body. At least one advisory committee member will be a member of each standing committee. Standing committees may add additional non-voting members as they see fit to accomplish the work being done by that group.
- b) Prehospital Operations
 - i) Draft and maintain protocols to serve as the basis for others throughout the state
 - ii) Address questions and needs that arise within the prehospital operational domain
 - iii) Advisory Committee representation will include EMS Medical Director, Ground EMS leader, and Air Medical Program Leader
- c) Blood Supply
 - i) Draft and maintain protocols to serve as the basis for whole blood supply and rotation
 - ii) Develop and administer marketing collaboration with blood product
 - iii) Advisory committee representation will include Blood Bank/Supplier Rep, the Rotation Center Blood Bank Rep, and one trauma program leader or medical director.
- d) Rotation Center Operations
 - i) Draft and maintain protocols to serve as the basis for rotation center protocols
 - ii) Address questions and needs that arise within the rotation center domain, including blood bank logistics and utilization within facilities
 - iii) Advisory committee representation will include the Rotation Center TMD, the Rotation Center Trauma Program Leader, and the Blood Bank Rep.
- e) Rural Implementation Committee
 - i) Advisory Committee representation will include the Rural Facility Rep and the EMS Medical Director
 - ii) Local implementation work groups from rural settings will be encouraged to participate in the rural implementation committee.

- iii) If the current Advisory Committee EMS Medical Director is over an urban agency, additional EMS representation from a rural agency will be solicited
- f) Quality Assurance Committee
 - i) EMS Medical Director
 - ii) Trauma Program Leader
 - iii) Blood Bank Rep (rotation center)
- g) Additional standing committees may be established by the advisory committee and will be approved by a vote of the CWBC
- 3) Description of Ad Hoc Local Implementation Work Group structure
 - a) Ad Hoc Local Implementation Work Groups will report directly to their local RETAC (or an adoptive RETAC if the local REATC has opted not to participate in the CWBC). They will work directly with the Advisory Committee to implement their own local whole blood program based on the framework created by the CWBC.
 - b) Each local implementation work group will identify a group lead who will be responsible for coordination and communication with the CWBC advisory committee.
 - c) Minimum representation for each ad-hoc local implementation work group will be an EMS or Rotation Site representative and a Rotation Center representative. Ideal work group membership would include the following:
 - i) For ground or air medical prehospital agencies working toward implementation:
 - (1) EMS/air medical program medical director
 - (2) EMS/air medical program leader (may be chief, captain, agency educator, or other agency leader as identified). This individual should have a strong understanding and ideally oversight or influence over their local agency daily operational activities.
 - (3) Rotation center representative. This individual will facilitate development of a rotation plan with the prehospital agency and their own and/or another rotation center.
 - ii) For rural facilities working toward implementation:
 - (1) Trauma medical director or ED medical director
 - (2) Trauma Program Manger or Coordinator, or an operational leader able to represent the facility
 - (3) Blood bank medical director
 - (4) Blood bank manager or director
 - (5) Rotation center representative. This individual will facilitate development of a rotation plan with the prehospital agency and their own and/or another rotation center.

Communication

The CWBC believes that transparency and inclusion are key values that will contribute to a successful coalition. In alignment with this belief, the following plan will guide communications within the coalition and outside of the coalition.

- The CWBC meetings will be open to all interested parties.
- The CWBC will maintain meeting agendas and minutes.
- The secretary will be responsible communication of meetings dates, times & locations, meeting
 agendas, and meeting minutes to all voting members as well as to any standing committee chairs,
 ad-hoc committee chairs, and specialty liaisons. Committee chairs will be responsible for
 distributing communications to their committees, and RETAC representatives will be responsible for
 distributing communications to their RETAC members.
- A publicly accessible platform will be used to post communications, announce meetings dates and times, and post contact information for people who would like to participate in the coalition or learn more about the work being done by the group.

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Definitions:

Rotation Site: A site where blood will be housed and made available to the patient population there for 14 days (or as determined by the advisory committee) before being rotated back to a higher volume rotation center. This could be a prehospital ground agency, an air medical agency, or a lower volume Level III or IV trauma center or non-designated hospital.

Rotation Center: A site where blood that has been housed at a rotation site will be brought back to for use prior to expiration. These sites are typically higher volume Level I or II trauma centers, but could be a higher volume Level III or IV center as identified by overall blood product utilization patterns.

Colorado Whole Blood Coalition

Organizational Structure



Foothills RETAC: Whole Blood Committee

Position paper on a Colorado Prehospital Whole Blood Program

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Introduction:

Prehospital administration of whole blood is one of the hottest topics in prehospital medicine. The life-saving benefits observed by the US Military over the last two decades are rapidly being translated into a similar survival advantage within the United States civilian community. Numerous EMS, Fire, or hospital-based programs across the country are administering whole blood with demonstrable, and lifesaving success. To date, most of these initiatives have been local or regional efforts. As presented during the Florida Whole Blood Coalition podcast on March 31, they estimate that approximately 10,000 units of blood were administered by 325 agencies in 2022. They also estimate that about 7.5-15% of EMS agencies nationwide have or are starting whole blood programs to date.

This White paper is meant to fulfill multiple purposes:

- 1.) Review the history of whole blood use in resuscitation of the injured.
- 2.) Review the pertinent literature regarding the utility of Whole blood in the prehospital setting.
- 3.) Propose a framework for a Colorado state-wide whole blood system implemented at all levels of patient care. This would include prehospital, transportation, and Trauma center levels.
- 4.) Provide an overview of national best-practice models utilizing prehospital whole blood. The specific program highlighted will be the Southwest Texas Regional Advisory Council (STRAC) whole blood program. The STRAC program is entering its 6th year and has already addressed many of the issues in establishing and maintaining a successful whole blood system.
- 5.) Provide, as an example, a structure for the implementation of a whole blood with in our RETAC

It is our position that the groups best suited to evaluate the need for a whole blood program are the local RETACS. The intent of the formation of the Colorado Whole Blood Coalition (CWBC) is to develop a collaborative best practice model that may be promulgated across the

state of Colorado through RETACS and on to EMS providers throughout the entire state. We feel that there are numerous advantages for all stakeholders having a unified set of policies and protocols and hope to solicit your input in this process.

Background:

Whole blood transfusion was part of the resuscitation for hemorrhagic shock from the first world war through the Vietnam conflict. Over 385,000 pints of blood were collected in the U.S. and transported to the European theatre alone in World War II. It wasn't until the Vietnam conflict that component therapy (fractionating blood into components of packed red blood cells, plasma, and platelets) became common. Component therapy was utilized to extend the storage life of blood and has never been demonstrated to offer a survival advantage for the patient. To the contrary, the use of whole blood has repeatedly been demonstrated to offer a distinct survival advantage for the seriously injured patient who requires transfusion.

The introduction of component therapy also resulted in an era of resuscitation marked by crystalloid resuscitation which we now know to have been harmful. For almost 20 years resuscitation was driven by normalizing the patient's blood pressure with crystalloid fluids such as lactated ringers or normal saline. This led us to the famous study by Bickell in 1994 that showed that patients who had no resuscitation did better than those resuscitated with crystalloids.¹ This initiated the era of permissive hypotension. While permissive hypotension is still an integral component in the management of hemorrhagic shock its effectiveness is dependent upon very rapid transport to definitive care.

Unfortunately, war continues to be the catalyst to improving trauma care. The extensive experience garnered by the US Military Medical Corps over the two decades of combat casualty care during Operation Iraqi Freedom and Operation Enduring Freedom has resulted in major changes to our understanding and treatment of hemorrhagic shock. The superiority of resuscitation with whole blood became established by as early as 2009.² Numerous additional studies have supported this concept to the extent that the military revised their Tactical Combat Casualty Care (TCCC) guidelines in 2014 to make whole blood the preferred means of resuscitation.

The second major change was the concept of bringing blood out of the hospital and forward to the injured patient in the prehospital setting. This concept of "blood far forward" has been proven to be dramatically effective. The THOR group (Trauma Hemostasis and Oxygenation Research Network) is a collaboration between military and civilian researchers and physicians that continues to drive a great deal of contemporary research on the use of whole blood in the field. One of the most significant studies to come out of this collaboration was the study by Col. Stacey Shackelford (Commander, US Military Joint Trauma System) and others released in 2016.³ This study evaluated mortality outcomes based upon the timing of blood transfusion in the prehospital setting. Their published results offer some of the most

significant support for a prehospital whole blood program.

This study demonstrated that the peak in early deaths from hemorrhagic shock occurred within 30 minutes. To improve survival, transfusion should be started as soon as possible at the site of injury and during transport. It cannot wait until the patient arrives at the hospital.



The patients that received transfused whole blood within 35 minutes of their injury had a statistically significant 6-fold improvement in short term survival and a 3-fold improvement in 30-day survival. This is demonstrated in tabular form on the next slide. The percentage of patients dying from hemorrhage decreased from 22.4% to 3.8% (6-fold improvement). These benefits extended throughout the first 30 days, where mortality was reduced from 26.9% to 9.4% (almost a 3-fold improvement). The number needed to treat to have one additional survivor at 30 days was less than or equal to 6.

| | Table 2. Medevac Study Population Post | -treatment Ch | aracteristics | & Outcon |
|---------------------------------------|---|-----------------------------|-----------------------------------|--------------------|
| Transfused on US | Unadjusted Post-treatment Between-Group Differences | Transfused Pre-hospital | Not Transfused Pre-hospital | n value* |
| MEDEVAC or not | *KIA (%) | 2 (3.8%) | 58 (20.3%) | 0.003* |
| within 30-35 min of injury | *Died (KIA + DOW) within 24 hours of MEDEVAC take-off from POI (%) | 2 (3.8%) 6-fold | 64 (22.4%) benefit | 0.001* |
| | *Died (KIA + DOW) within 30 days (%) | 5 (9.4%) 3-fold b | 77 (26.9%) enefit, NN1 | 0.005* 6 |
| | *Tranexamic Acid [TXA] (%) | 48 (90.6%) | 144 (50.3%) | < 0.001* |
| | Documented shock [SBP<90, HR>120 or shock index >0.9] upon ED arrival (%) | N=52 39 (75%) | N=233 137 (63%) | 0.110 |
| | *Massive Transfusion [>10 units/24hrs] (%) | 40 (75%) | 119 (42%) | < 0.001* |
| | ISS: Median (IQR) | 29 (17, 36) | 24 (17, 36) | 0.179 |
| | AIS Score indicating torso hemorrhage (%) | 22 (41.5%) | 108 (37.8%) | 0.646 |
| Shackelford, Del Junco MHSRS 2016. | *Statistically significant at <0.05 level | by Fisher's exac | t test. | |

This has been corroborated in Civilian Studies as well, exemplified by this work from Alarhayem, et al:





This study mirrors Shackelford's work in that the rise in mortality begins as early as 0-15 minutes for severe AIS scores and peaks in the 16-30 minute group. Also note that if the prehospital phase is prolonged, even less severe injuries begin to have a significant mortality.

The third major development in the use of prehospital whole blood driven by the military's experience addresses the issue of not having whole blood available for transfusion. This began with the 75th Ranger Regiment's ROLO program in 2015. Instead of screening the unit of blood to be transfused, they screen potential donors and then use them as a walking blood bank to deliver warm whole blood at the point of injury. To date, over 18,000 units of blood have been transfused by the US military since 2016. This has been accomplished without any major transfusion reactions. This program has been extraordinarily successful and has spread throughout the military and into some civilian settings.

Providing whole blood at the point of injury has been shown to markedly increase survival and reduce the overall need for blood products. A large multi-center Study by Hazelton, et al, demonstrated a 9% reduction in bleeding complications and mortality was reduced by 48%.⁵ Brill, et al⁶, compared the outcome of patients receiving prehospital whole blood to those who did not. They found a 4-fold increase in survival and a 60% reduction in overall transfusions in those receiving prehospital blood even though those patients had higher injury severity scores, lower blood pressures, and higher initial venous lactate levels.⁵ Other studies have shown

similar results with increased survival, lower total transfusion volumes, lower major complications, and shorter hospital stays.⁷⁻⁹

Prehospital whole blood has also been shown to improve outcomes with other forms of hemorrhagic shock, including gastrointestinal hemorrhage and obstetric related hemorrhage. Analysis of the South Texas Regional Advisory Program's (STRAC) first 916 patients showed that almost 40% of their prehospital transfusions were for atraumatic hemorrhagic shock.¹⁰

It has also been shown that even Rh-negative (Rh-) women of child bearing age can benefit from receiving O-positive whole blood. While there is a risk of developing auto-immunization against Rh- antibodies, mitigation strategies can reduce this to 3-6% of O+ transfusions.¹¹ Additionally, therapies for the treatment of hemolytic disease of the newborn (HDN) have improved to a point where severe HDN occurs in only 0.3-6.5% of pregnancies in women who have seroconverted.¹² This suggests it would take approximately 250 years to have between 3 and 30 cases of severe HDN⁻ and there would be approximately 500 deaths from hemorrhage of reproductive age women over the same period of time⁻¹²

Whole blood has been proven to be the best means of resuscitating hemorrhagic shock prior to definitive management by a surgeon. It is safe, effective, and it has been demonstrated that it can and should be administered by prehospital providers as early as possible.

Colorado State-Wide Prehospital Whole Blood System

Goal:

To provide prehospital administered whole blood to patients in hemorrhagic shock across the state of Colorado.

General Considerations:

- 1) A state-wide system should be based on the 11 RETACs and the program should be administered by the individual RETACs.
 - a. The decision to participate, and to what degree, should be based solely within the RETAC.
 - b. If a RETAC doesn't wish to participate, but agencies within the RETAC do wish to participate they will be assigned to the closest RETAC for administrative purposes only.
- 2) It is also our belief that if a RETAC decides to participate, the protocols should be agreed upon by all participating members, and that all participating RETACs should use the same protocols.
 - a. This will facilitate our interactions with both our hospital partners as well as our blood suppliers.
 - b. It will standardize interactions between prehospital providers and hospital staffs at handoffs or transfers.
 - c. It will make both teaching and QC/QI easier for both our providers and their medical direction all the way from the agency to the state level.
- 3) It is also our belief that maximizing whole blood availability for our rotor wing aeromedical services needs to be a priority as the system develops.
 - a. Having rotor wing aircraft stocked with blood at all times will minimize the geographic inequities in our state and allow a higher level of care for our rural and frontier residents.

Program Design:

The delivery of whole blood is based on 5 tiers:

- 1) Tier 1A rotor wing delivered Cold whole blood
- 2) Tier 1B Ground unit delivered cold whole blood
- 3) Tier 2 Ground blood picked up from a hospital and delivered to the scene
- 4) Tier 3 walking blood bank delivered warm blood
- 5) Tier 4 non-participation

The blood donation and collection system would be the Colorado Whole Blood Heroes, or just "Heroes" program.

Tier 1A Rotor wing delivered cold whole blood:

- 1) These programs already exist, as we look at a RETAC based program our goal is to provide support and integration with our prehospital providers particularly our more isolated agencies.
- 2) Our second goal is to develop a system similar San Antonio's Brothers in Arms program in our "Heroes" program that can ensure that the availability of whole blood is not the rate limiting factor for this means of blood delivery.
- This will require creative thinking on how to best to rotate blood out of more geographically remote flight bases back to hospitals where it can be used before it expires.
- 4) Advantages:
 - a. Aside from Tier 3 blood, this is the only way to deliver blood to more remote settings in a timely fashion (and would negate the need for tier 3 blood in most instances)
 - b. Bringing a flight crew and their expertise to the point of injury or a rendezvous point to assist with the patient's resuscitation beyond just simply administering blood.
- 5) Disadvantages:
 - a. Putting an aircrew at risk
 - i. Takeoff, landing, urban, and mountain flying hazards
 - b. Weather:
 - i. Depending on your location weather may prohibit flying and necessitate other means of blood delivery
 - 1. Particularly for our mountain RETACS

Figure 1 is a map of the current 21 aeromedical helicopters operating in Colorado with a 50mile radius marked out around their base (OUR very conservative estimate of how far you could get with an immediate "Chopper Go" and land and open the door with blood within 30 min under optimal conditions). As can be seen, even though this is the fastest way to move blood to our rural areas, a sizeable amount of the state remains outside of the 30 minute treatment window suggested by Dr. Shackelford's data. This map also demonstrates the geographic separation in our state caused by the mountain ranges of the continental divide and the San Juans. Lastly, some of our poorest counties in terms of EMS resources in the San Luis valley, as well as some of our most remote populations in the extreme northwest and southeast corners of the state will not have the access to rotor wing aircraft or the ability to do ground based (Tier 1B) Blood delivery when compared to other areas of the state. Please note, I did not include helicopters based outside of Colorado such as Lifeline 2 in Cheyenne, Classic 7 in Moab, and Classic 1 in Vernal Utah as their medical direction is outside of Colorado, but they certainly contribute to the aeromedical coverage of our state particularly in the far west. Reach 29 in Salida and Reach 71 in Alamosa were excluded as they do not carry blood products.



Figure 1

Tier 1B Ground unit delivered cold whole blood

- 1) These would be based on EMS units with close enough proximity to hospitals that could serve as the facilities to participate in a blood rotation system.
- 2) There are many circumstances where they could get to a scene just as fast or faster and with less risk than flying blood to the scene
- 3) Advantages:
 - a. No risk to a flight crew
 - b. May require less time
 - c. Local community involvement will help the Heroes program to recruit and retain blood donors (enhances a sense of community involvement)
- 4) Disadvantages:
 - a. May have less opportunity to give blood then a flight crew, will have more time and cost spent rotating blood.
 - b. Geography, traffic, and weather can all limit the range of a ground-based ambulance to provide blood in a timely fashion
 - c. Will require more training secondary to less frequent blood administration (High acuity low occurrence event)

Tier 2 Ground blood picked up from a hospital and delivered to the scene

- 1) Already performed in Colorado
- 2) If the prehospital agency is close to the hospital this may not cost too much time
- 3) Qualified prehospital units could "check out" blood from a participating hospital.
 - a. Ideal means to stage blood with tactical units
 - b. May be possible to design a kit that includes the blood warmer and possibly a blood pump to diffuse the capital outlay on transfusion related equipment.
 - c. Has already been used to provide blood for use in MCI settings by STRAC.
- 4) Advantages:
 - a. The blood is stored by the hospital, doesn't require a rotation system.
 - b. May reduce the costs as compared to a Tier 1B ground delivered blood system.
 - c. Strengthens community relations with the hospital.
- 5) Disadvantages:
 - a. Size and location of the facility would determine the availability of whole blood or blood components.
 - b. Will require aggressive hospital policies to provide blood in a timely fashion.
 - c. Requires a short distance between the EMS agency and the hospital.

Tier 3 Walking blood bank delivered warm whole blood

- This is the only tier that does not use cold stored whole blood as is used in tiers 1A, 1B, and 2. Instead of delivering a unit of blood to be transfused that has been tested, you are collecting blood from individuals at the scene who have been previously tested and administering it without additional testing.
 - a. This is the method of choice for administering whole blood when cold stored whole blood is unavailable.
 - b. It has been demonstrated to be both safe and effective by both military and civilian agencies.
- 2) This could serve as a backstop to the other tiers if blood is unavailable, as well as providing additional supplies for surges or mass casualty incidents.
- 3) It could serve as the primary means of blood delivery to areas that are too remote to have a rotation system or timely aeromedical blood delivery.
- 4) Advantages:
 - a. Has the potential to be the most reliable of the different tiers of whole blood
 - b. Has the lowest costs, all you need is a transfusion kit (approx. \$100/pt)
 i. No storage or rotation costs
 - c. May be able to be started the most quickly of all the tiers
 - d. Is not dependent upon hospital usage
- 5) Disadvantages:
 - a. While it has been demonstrated to be safe, it is not as safe as transfusing a screened unit of blood.
 - b. It asks a lot of the donor.

Tier 4 Non-participation

- 1) This is fine, this program may not be for everyone.
- 2) If a RETAC were to join at a later date, they would have to either:
 - a. Join using the protocols already being used by the other RETACs.
 - b. Persuade the existing coalition to change their protocols.

Discussion

The state-wide system would encourage the individual RETACs to choose which of the tiers they wish to use. The protocols within a given tier will be standardized for the reasons outlined in the General discussion.

Urban and suburban systems with short transport times might well be able to function on Tier 1A alone, possibly only using tier 3 donors for MCIs.

Foothills and mountain communities could use a combination of tiers 1-3to ensure the availability of blood at the point of injury in the shortest amount of time. The ability of foothills, mountain, and rural communities to participate in a blood rotation system would largely depend upon their distance from larger hospitals or systems that use enough blood to absorb the whole blood rotating in from prehospital systems.

Rural and frontier RETACS might choose Tier 1 rotor wing delivery backed up with tier 3 blood donors and tier 2 hospital sites if available.

Our most isolated sites might have to use Tier 1A blood accepting longer transport times combined with Tier 3 donors.

While aeromedical systems are integral to a state-wide system, they would face some of the most significant logistical difficulties. They have the greatest potential to be transporting or administering whole blood to patients that might be delivered to a system that uses a different blood supplier. This will require policies and procedures to facilitate these types of transfers to minimize the possibility of whole blood wastage.

The Colorado Whole Blood Coalition will take input from the RETACs and then decide upon standardized protocols for each tier. Once the protocols are agreed upon, individual medical directors can then request the appropriate state waivers. While the number of waivers the state will see will be substantial, the waivers themselves should be identical. This should only result in the need to only consider 3 waivers, one for each tier administering blood. This process is scalable and Tier 1A-3 sites or agencies could be added as funding and blood supplies grow.

Our vision for a unified state-wide system incorporates all tiers to provide the most comprehensive coverage possible for the citizens of Colorado. Every patient, from those who live in our most densely populated urban areas to those who live in our most remote frontier counties could potentially receive the therapy that is the proven best practice for the treatment of hemorrhagic shock.

Triggers to initiate prehospital whole blood transfusion:

- 1) Indications for Tier 1A, Tier 1B, or Tier 2 transfusions would include any of the following criteria:
 - a. Signs of hemorrhagic shock must be present.
 - b. Systolic BP <90
 - c. Heart rate >120
 - d. Shock index >1
 - e. ETCO2 < 25

- 2) Indications for Tier 3 Transfusion would include any of the following criteria:
 - a. Signs of Hemorrhagic shock must be present.
 - b. Unavailability of Tier 1A, 1B, or Tier 2 blood
 - c. Tier 1A, 1B, or Tier 2 blood not available for > 30 minutes
 - d. Blood available < 30 minutes but severe physiologic criteria
 - i. Systolic blood pressure < 80
 - ii. Heart rate > 135
 - iii. Shock index >1.25
 - iv. ETCO2 <25

The "Heroes" program

The strength of any whole blood program is absolutely dependent upon the ability to collect and distribute whole blood. One of the keys to STRAC's success is their ability to engage their community and develop a pool of dedicated donors. STRAC's ability to engage the city of San Antonio with The Brothers in Arms blood donation program, since renamed "Heroes in Arms", fostered a sense of community and participation among their donors that is exemplary. They have over 4000 donors who provided 11,000 units of blood last year. To accomplish the goals of a statewide whole blood system would require Colorado to develop a commensurately larger system.

The operational plan for the Heroes program would be to establish and publicize it as an entity. The initial blood sign-up for the program could be directed at prehospital, EMS, Police and Fire agencies for individuals known or thought to have O+ blood types. This would be extended to the general community as quickly as possible.

Donors identified as O+ would then be screened for anti-A and anti-B titers. It is anticipated that about 85% of donors would be low titer. This blood would be used to stock the receiving hospitals with the appropriate inventory of whole blood.

Once we have established a pool of eligible donors the goal would be to build a donation schedule for these individuals to smooth out the blood donation process and deliver a steady stream of donations. Establishing a system that provides blood donations at a sustainable and predictable rate is necessary for our partnered blood suppliers.

As we establish an inventory of whole blood, the next step would be to begin rotating these blood units into the field. As previously discussed, our goals will be to build a system that can deliver adequate supplies of whole blood to:

- 1) rotor-wing aeromedical services Tier 1
- 2) Ground based units providing Tier 1A blood
- 3) Hospitals providing Tier 2 blood
- 4) Surge events or MCI events

While much of our discussion has been on the obstacles created by Colorado's geography and variable population density, some of these factors are favorable to a whole blood collection program. Eighty two percent of Colorado's 5.8 million residents live along the front range making it easier to go to a centralized blood collection center. The strong community spirit in many of our mountain and rural communities will support local blood drives with distributed blood collection efforts. This combination will allow for adequate whole blood supplies to meet the needs of a state-wide whole blood program.

The STRAC model

One of the most successful, and most innovative civilian programs in the United States is the South Texas Regional Advisory Council (STRAC) program. This was started in 2018, and over the last 6 years over 1000 patients have received prehospital transfusions of whole blood. They identified the same major issues as we have, as outlined in their initial proposal:



Rationale: Coagulopathy & the "Golden Hour"





They Began the "Brothers in Arms" program in 2018



Their one RAC (regional advisory Council) occupies as much acreage as ¼ of the state of Colorado. It is similar in that most of their counties are frontier or rural with long transport times. Important differences are that there are only 2 level I trauma centers, both in San Antonio. All major trauma patients are transported there. The geography is very different from Colorado being composed almost exclusively of plains with altitudes varying from 600-1000 feet above sea level. They have 5 aeromedical providers with 18 rotor wing aircraft serving the area. They utilize a rotation system for their whole blood, as detailed below.



As shown above, blood is initially in the field for 2 weeks, it is then rotated back to one of their two Level I trauma centers with the expectation it will be used in the next 3 weeks. The Rotation system is one of the greatest strengths of the STRAC system. The program had its 5-year anniversary in January of 2023. They have treated over 1000 prehospital patients to date . They have also established processes and protocols that are detailed and precise and we feel have broad applicability to our program.

STRAC Tenants to Developing a Whole Blood Program

This largely applies to hospital affiliated programs as we will discuss in a bit, but these fundamental pieces have some applicability to all prehospital whole blood programs. This slide summarizes the relationships that must exist in harmony to make a prehospital whole blood program work:



Buy-in from all groups and balanced participation by participants is necessary for this process to work. each of these groups to make this work. Each group needs the expertise of the other groups to achieve the goal of providing the best possible care for the patient. Each of these groups represent very different lines of thought and modes of operation. Regulatory and safety concerns have tremendous importance to our blood bank and pathology partners. As stewards they are also responsible for providing optimal care and minimizing any potential waste of blood products. Like all organizations providing a specialized product, blood centers have production schedules, supply lines, and inventory issues, and other complex problems. Prehospital provider's focus on patient care and the systems that reliably provide that care need to be understood as well. To achieve the proven benefits of prehospital whole blood administration requires the cooperation of all 3 groups.

Hospital Blood Bank/Pathologist/Laboratory

Meeting the stringent needs of the hospital blood bank and staff requires that we as prehospital providers can conform to the policies set out by the Association for the Advancement of Blood & Biotherapies, formally the American Association of Blood Banks, and more commonly known as the AABB. They provide the regulation and oversight for blood banking, testing, and blood administration. This results in some overarching issues as well as several specific operational issues.

The operational issues fit into two major areas. The first is accurate identification of the blood product. This is accomplished by pre-issue confirmation of ABO/Rh of the blood unit (required by AABB standard 5.12) either prior to or at the time of checking a unit of blood out from the blood bank.



STBTC in the above slide refers to the South Texas Blood and Tissue Center who is the blood supplier for STRAC. This would be performed by the blood supplier in Colorado.

The unit of blood than is identified with a tie tag shown on the next slide which identifies that unit as non-crossmatched whole blood as well as instructions on returning the blood container to the blood bank (for testing).



The other major operational issue for both the hospital and prehospital providers is that whole blood must be maintained at a temperature between 1-6 degrees Centigrade the entire time it is outside of the hospital. This is the only way it can potentially be returned to the blood bank. This requires a validated storage system and two means of monitoring to ensure that the blood does not exceed the approved temperature range (AABB standard 5.1.8.2.1) Regulations also require validation of the storage system. STRAC uses a pelican storage case with the Credo insert. These inserts are changed out every 24 hours with one that has been in a standard freezer. They have been demonstrated to maintain temperatures between 1-6 degrees C for 24 hours. The blood is continuously monitored with a "Temp-stick" or similar device that is kept in the cooler with the blood. This tracks the temperature and maintains a log of that blood unit's temperature. It will also alarm if the temperature starts to rise.

These are just examples of the technologies needed to maintain and monitor the appropriate temperature. They are not meant to be an endorsement of any particular brand. There are other validated commercial products available.

Real-time Temperature Monitoring





These pictures show the Pelican case, Credo insert, and the Temp-stick monitoring device



In San Antonio, real-time temperature data is also sent to STRAC's Comm Center. Lacking such a facility in Colorado, temperature data would need to be sent to multiple parties within each agency to ensure that blood temperatures are safely monitored.

The last line of temperature monitoring is a temperature sensitive marker on the blood bag itself that will change color from white to red if the temperature exceeds 10 degrees (blood is considered unusable at that temperature.



The other critical issue is minimizing any potential waste of whole blood. Blood is always a commodity that is in short supply, and not using it within its lifespan needs to be reduced as much as possible. One of the Strengths of STRAC's program is that they have reduced their wastage to consistently under 3% and they usually achieve close to 1%. This requires a two-pronged effort. First, the hospital needs to use whole blood for as many indications as is clinically appropriate. This will maximize the number of unused whole blood units that can be returned from the field if they are unused. The second prong is that prehospital systems can only place as much blood in the field as will be used before it expires after being returned to the hospital. It is better to start with fewer units of blood in the field and have less wastage, then it is to start too large and have blood wasted after return to the hospital. This can work on a large scale but it must be carefully managed. This is shown in STRAC's history where wastage was very high the first year but has been under 3% since that time.



This graph demonstrates that while collection of low titer O whole blood (LTOWB) by STRAC and South Texas Blood and Tissue has increased over 5-fold since 2018, they have been able to keep wastage under 3% since year 2 of the program.

Blood Suppliers

Our blood supplier for much of Colorado is Vitalant, inc. They are the second largest blood supplier in the US, and supply much of the Midwest and high plains states. They have been very responsive to our initial efforts to create a Colorado prehospital whole blood program and understand how beneficial it is for our patient's. They are not our only blood supplier and statewide protocols will need to be developed for all of our blood suppliers. They share a major issue with the blood bank, in that they want to minimize any wasted product. What is wasted in a prehospital program could be used for other patients.

Our blood suppliers also need a steady input of blood into the system. A once every 6 months blood drive even if it's huge doesn't do them nearly as much good as a steady daily supply of donors. This will require conscious efforts particularly from our more geographically isolated communities. This is one of the now "Heroes in arms" program's greatest strengths, they deliver dedicated donors, that keep their appointments and fuel their program as shown below with their 2022 data.



The development of a blood supply program analogous to what STRAC has done with the "Brothers in Arms" program will be an essential component of any comprehensive plan to have a steady supply of whole blood available for prehospital use.

Example of a RETAC Level Whole Blood Program

Foothills RETAC Whole Blood Program

Goals:

- 1) To provide prehospital whole blood to patients within the RETAC boundaries in a safe and reliable fashion
- 2) To provide prehospital whole blood in the settings of MCI, SAR, and surge situations

Overall Plan:

- 1) The RETAC will plan on using Tier 1A, Tier 1B, possibly Tier 2, and under specific circumstances, Tier 3 whole blood.
- 2) The RETAC whole blood committee will decide where available Tier 1A and Tier 2 blood units will be staged within the RETAC.
- The decision of which tier of blood to be used will be made by the medical provider on scene per established protocol, and blood will only be administered per established protocol.
- 4) All encounters where blood was administered will be evaluated for QC/QI and will generate a UCR and appropriate state waiver reporting.
- 5) Individual agencies will decide which of their staff will be trained to give both cold stored whole blood and warm fresh whole blood transfusions. Transfusions will only be given by individuals who have completed the appropriate training.
- 6) Administration of whole blood cannot delay the transportation of the patient to definitive care.
- 7) Consider TXA and calcium gluconate per protocol and/or agency medical direction.

Program Specifics

- 1) Treatment of hemorrhagic shock would be the only indication.
 - a. We will need to decide about traumatic cardiac arrest and GSW to the head.
- 2) The only contraindication would be a confirmed religious or personal desire not to receive blood products.
- 3) Indications for Tier 1A, 1A, and Tier 2 transfusions:
 - a. Signs of hemorrhagic shock must be present
 - b. Systolic BP <90
 - c. Heart rate >120
 - d. Shock index >1

- e. ETCO2 < 25
- 4) Indications for Tier 3 Transfusion:
 - a. Signs of Hemorrhagic shock must be present
 - b. Unavailability of Tier 1 or Tier 2 blood
 - c. Tier 1 blood not available for > 30 minutes
 - d. Blood available < 30 minutes but severe physiologic criteria
 - i. Systolic blood pressure < 80
 - ii. Heart rate > 135
 - iii. Shock index >1.25
 - iv. ETCO2 <25
- 5) No whole blood unit will be transfused if it has been documented either by Temp-stick data or Safe-T-Vue 10 color metric sticker to have been outside of temperature range.
- 6) All Tier 1A, Tier 1B, and Tier 2 transfusions will use a blood warmer.
- 7) Regardless of which transfusion tier is used, the blood container will be brought with the patient to the hospital for additional testing.
- 8) The storage and transportation of Tier 1A, 1B, and Tier 2 whole blood will be per established protocol consistent with standardized state-wide protocols.
- 9) Any administration of whole blood will generate a UCR with 100% QC/QI and standard waivered acts reporting.

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