


Walking blood bank: a plan to ensure self-sufficiency in an era of blood shortage

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SUMMARY

Mass casualty incidents and massive transfusion requirements continue to plague the USA with hemorrhage remaining the number one cause of death in trauma. The unfortunate reality of numerous mass shootings in Southwest Texas has led to the need for a way in which to provide blood during these events as rapidly as it is required. Multiple agencies within the Southwest Texas system have united to help provide this life-saving blood to people when they need it most. This effort began with the development of a system for safe, efficient, and now widespread use of whole blood in the region. After demonstrating the success of delivering large quantities of blood during the Uvalde shooting, we have begun to develop a walking blood bank that is similar to what the military uses on the battlefield. The concept behind this initiative is to have a cohort of whole blood donors who are preselected to join the program which is now dubbed 'Heroes in Arms'. These donors will be called upon to donate whole blood during a massive transfusion event. Their blood will be rapidly screened prior to transfusion to the patient. This blood will still undergo the normal rigorous testing and, should any potentially transmissible diseases be discovered post-transfusion, the individual who received that product will be treated accordingly. Given the low rate of transmissible disease among this preselected population, combined with rapid screening prior to transfusion, the risk of a person receiving a transmissible disease is insignificant in comparison to the benefit of having blood to transfuse during hemorrhage. This model is a promising collaborative effort to provide in a timely and sufficient blood product in cases of major need which will consequently minimize the number of traumatically injured civilian patients who die from hemorrhage.

BACKGROUND

There are more than two mass shootings¹ and even more mass casualty incidents (MCIs) throughout the USA every single day. Hemorrhage remains the most common cause of death in trauma.² Southwest Texas has faced numerous MCIs including Sutherland Springs church shooting (26 dead and 22 injured) in 2017, Midland and Odessa (8 dead and 25 injured) and El Paso (23 dead and 22 injured) in 2019; and Uvalde (19 children and 2 adults dead) in 2022. This is in addition to a number of motor vehicle crash-related MCIs. The ability to rapidly obtain blood and transfuse injured trauma patients

with oxygen-carrying and clot-forming blood products remains of utmost importance.³

Blood is a precious commodity. In January 2022, the American Red Cross declared a 'blood crisis' for the first time in over 80 years. Only 5% of eligible people donate blood and about half of all donations come from individuals over 50 years old. This shortage was exacerbated by decreased supply during COVID-19 and the supply has still not returned to pre-pandemic levels,⁴ reflecting the wide gap between demand and supply that can only increase during MCIs.⁵

Low titer type-O whole blood (LTOWB) has recently become popular in the civilian population due to successes in military use and to numerous advantages it has over component blood resuscitation for hemorrhage. Since this product can be transfused without component separation, time from donation to administration can be significantly reduced, which has several practical advantages.⁶

The concept of a walking blood bank (WBB) was implemented as early as World War I. During the conflicts in southwest Asia, this capability was designed to increase available supply of LTOWB to individuals after combat injury in areas without nearby medical facilities and it has been developed in Norway as part of their blood preparedness project.⁷ In the most recent years, the blood supply has become more vulnerable despite multiple efforts for maximum efficiency. However, many points of failure at different levels have been identified and could be catastrophic with supply chain failures during a massive transfusion crisis emphasizing the importance of a civilian WBB as an emergency preparedness plan to increase blood availability in the site of need.⁸

Thus, although fixed donation facilities remain the mainstay for blood collection in times of crisis, more blood may be needed than can be supplied in those traditional times. The utility of having a mobile facility for blood donation is equally important in the civilian sector for the contingency of MCI. The southwest region of Texas is developing a civilian system, whereby a mobile donation facility could be transported to where the blood is needed, and local members of the WBB can donate on-site to provide the blood as expeditious of a manner as possible to collect extra units during mass transfusion disasters. This article will describe the implementation of a civilian WBB that can be activated to promptly provide LTOWB to

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individuals in hemorrhagic shock due to mass shootings and MCIs.

METHODS

The Southwest Texas Regional Advisory Council (STRAC) covers a 26 000 square mile portion of Southwest Texas that includes the seventh largest city in the USA.⁹ This area includes a mixture of urban, rural and frontier areas where a large portion includes the US-Mexico border with 74 hospitals, two level 1 trauma centers and over 70 EMS agencies with a total population of about 2.5 million.

The region's prehospital providers are supplied with 50–60 units of LTOWB. In addition, the civilian level 1 trauma center (University Hospital) routinely has on average 50 units of whole blood in stock supplementing the regional blood supplier that regularly has an inventory that exceeds 60 units, sharing a total of 150 units of LTOWB to distribute in the region when the need arises. We aimed to create a system that augments the supply of LTOWB. To combat this, we assessed whether the local population of female donors could potentially be included as LTOWB donors despite historically higher rates of human leukocyte antigen (HLA) antibody positivity which is known to increase the risk for transfusion related acute lung injury (TRALI). This was undertaken to supplement our Heroes in Arms donor pool, previously known as Brothers in Arms.

The Heroes in Arms pre-screened donors act as our established emergency donor pool, who yearly undergo transfusion transmittable disease testing (HIV, hepatitis B and hepatitis C), antibody titer testing and a face-to-face interview with trained blood bank personnel. One goal of the blood supply and transfusion system here is to develop a rapid screening that could be utilized to move from blood donation to LTOWB transfusion as quickly as possible while still maintaining the high safety profile expected of blood transfusions in the USA. A coordinated effort between multiple local agencies was utilized to optimize the screening protocol for LTOWB. The region has endeavored to enhance the potential LTOWB donor pool by screening and including women, even those who have previously been pregnant.

To further support the use of rapidly screened LTOWB from an individual in the WBB, the local database was investigated to determine the rate of blood donation deferrals. Among the 4013 LTOWB donors in 2022, only 12% were deferred and the majority (9%) were deferred due to baseline hemoglobin level. Of the 4013 LTOWB donors between 2020 and 2023, only 2% were permanently deferred and half of all deferrals are made prior to donation using a screening questionnaire. In cases where the individuals do not pass the questionnaire, the blood is drawn and put on quarantine before the standard testing process is performed. Additionally, only 1% of all LTOWB in 2022 was discarded due to a positive test which includes individuals who were not prescreened. Collectively, prescreened individuals from a population that already has a low rate of LTOWB deferrals with minimal post-donation testing positivity among all donors supports the safety of using a WBB particularly given the potentially lethal outcomes if an individual was unable to receive a blood transfusion due to lack of local supply.

Coordinated efforts are also made to augment LTOWB deployment using personnel from the local blood bank, ground and flight prehospital teams, and multidisciplinary groups involved in healthcare outreach in order to establish a protocol that would allow for LTOWB to be available where it is needed and when it is needed.

RESULTS

The local blood bank usually receives approximately 25 donors on a typical day. These blood products are put through a thorough screening process that takes approximately 18–24 hours to complete. The South Texas Blood and Tissue Center (STBTC) has screened over 10 000 potential donors, with approximately 4400 individuals in the donor pool. Women were historically not included as LTOWB donors due to HLA antibodies that are occasionally a result of exposure during pregnancy as their antibodies are known to increase the rates of TRALI. Some blood bank systems have included women only if they were not previously pregnant. By January 2023, STBTC had screened 2151 previously pregnant females to donate as part of the program known as Heroes in Arms and found that remarkably only 17% were HLA antibody positive. Therefore, 83% of previously pregnant women are now theoretically eligible for LTOWB donation, significantly increasing our potential donor population.

A local protocol was developed to support blood requirements during MCI when there is a potential for exhaustion of the regional supply. Blood products are then mobilized to the appropriate receiving facilities and prehospital personnel. When local blood supply begins to dwindle, there is a system by which interstate facilities can assist one another and reserve a portion of blood to be delivered quickly to a blood bank that has a sudden need for increased blood transfusions. The Blood Emergency Readiness Corps of over 12 blood suppliers was developed as a joined effort to prepare for mass transfusion disasters.¹⁰ However, a major limitation is the lack of local sufficiency to ensure a timely delivery of the product before the median time to death in massively bleeding patients, which is under 2 hours, which was highlighted by Holcomb on his article 'Civilian walking blood bank emergency preparedness plan'.¹¹ Therefore, a local nearly instantaneous increase in blood supply using a WBB is being developed within our system.

Our coordinated locoregional effort is to create a WBB that will rapidly test blood for communicable diseases prior to transfusion to a patient in a scenario where blood supply becomes critical. This includes activation of our locoregional campaign to quickly notify our Heroes in Arms donors who are willing to give blood on short notice (figure 1).

This collaboration will allow for blood to be collected from the prequalified donor pool—Heroes in Arms, rapidly screened, and then administer the blood from the donor as quickly as it is needed. This is a method used in far forward military scenarios using rapid viral testing cards not yet approved by the Food and Drug Administration.¹² This process will further decrease the incidence of blood transmissible infections. By all projections, there would be an exceptionally low risk of having a transfusion-related disease transmitted from the known and previously tested donor pool.

If in the case that an individual receives LTOWB that later tests positive for a communicable disease, the individual (or their medical power of attorney) and the providers caring for the patient will be notified immediately. Additionally, the local blood bank leadership and health systems will be notified so that the event can undergo an expedited root cause analysis. This effort will identify a possible underlying cause for what may have resulted in the donor becoming positive for a communicable disease despite a history of negative prior screens. This investigation will be used to identify others within the regional WBB who may also be exposed to a similar source in the future. The donor will be notified, and appropriate treatment initiated immediately either by their own primary care physician or

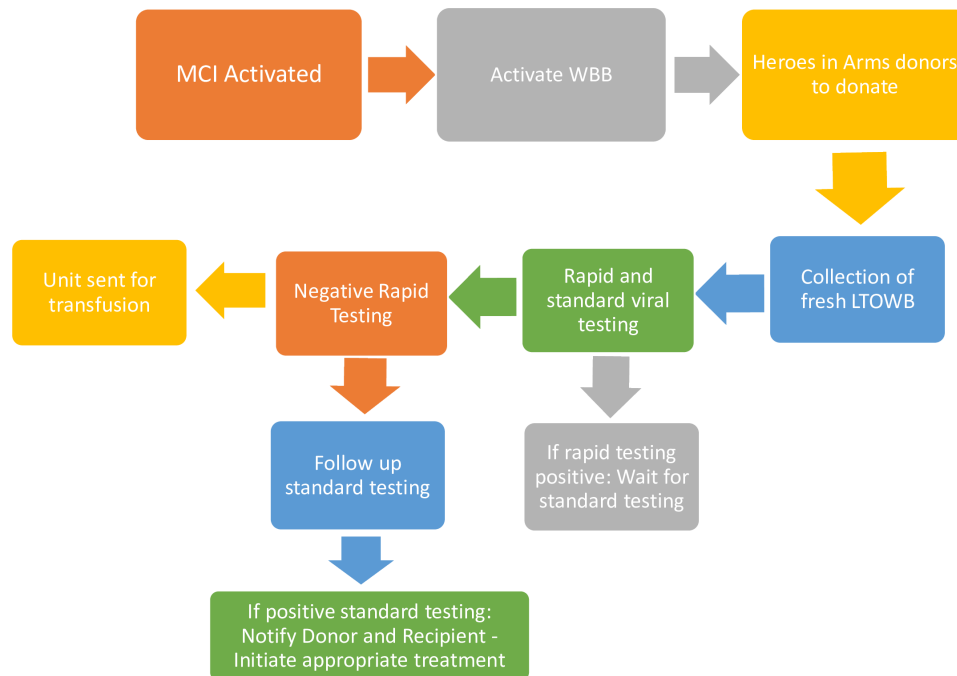


Figure 1 Walking blood bank workflow. LTOWB, low titer type-O whole blood; MCI, mass casualty incident; WBB, walking blood bank.

one of our regional medical centers. This information will be stored securely, and the event will be reported to the appropriate regional, state, and federal authorities as is standard practice with any blood transfusion-related events. This data collection will also include the effect on the patient who was exposed whether the individual formally contracts the disease they were exposed to. Furthermore, any transfusion-related reactions from LTOWB that were negative for transmissible diseases will be tracked and reported in the same manner. By default, the institution caring for the patient who received the unit of LTOWB will initiate treatment and then coordinate ongoing treatment after discharge if necessary.

One of the hallmarks of an effective blood donation program is to ensure that waste is kept to a minimum. A theoretical downfall of a WBB and LTOWB donation is that one wasted LTOWB equates to three wasted units of blood components. However, we have implemented an efficient local system that ensures blood products are cycled such that they are administered without any additional modification. The regional system generally gives prehospital personnel the newest blood, which they will store cold and take to the field for approximately 2 weeks prior to the unit being exchanged for a new one while the 2-week-old unit is transferred to a high-volume hospital such as a level 1 trauma center. This comes down to approximately 1% wasted units due to expiration date or incorrect storage, which is better than component therapy blood waste (figure 2).

Regarding regulatory approval, currently the Office of Blood Research and Review (OBRR) within the FDA is responsible for ensuring the safety, efficacy, and availability of blood components intended for transfusion and further manufacture. Emergency preparedness is a policy in development without current active regulations in relation to the development or implementation of a WBB. The OBRR has established a multilayer approach to blood safety that includes: (1) Donor screening to select eligible donor, which is formally implemented to our donor pool from the Heroes in Arms program answer the questionnaire and undergo evaluation to ensure they are safe to donate; (2) Donor deferral registry; (3) Infectious diseases testing—our donor pool

is routinely screened with standard laboratory testing and the rapid screening is an additional testing we are performing in case donors that have sero-converted since their last standard testing was performed. This in addition to the repeat standard testing performed on the blood donation to the WBB during the emergency need that would be done after the fact; (4) The blood bank monitors and takes corrective actions that address any problems or deficiencies encountered. Last, (5) the blood is quarantined until its tested and is shown to be free of infectious agents. This item would not be followed when the WBB is in action due to the time constraints in order to save life; this would fall into the category of emergency preparedness that has currently no regulatory guidance.^{13 14} A request for an exception and alternative procedure to expedite transfusion in life-threatening emergencies under Code of Federal Regulations (CFR) Title 21 part 606.160 (b)(3)(v) which deals with emergency release of blood products and 21CFR 610.40 (a)(2)(iii)(A) which discusses testing requirements and relative risk of transfusion transmissible infections should be performed. On these unique circumstances, it should be initiated orally and followed by a written request within 5 working days.

DISCUSSION

As mentioned above, there are many steps to consider when developing blood bank and WBB as part of an emergency preparedness program. Here, we described our experiences and challenges met during the development of our locoregional process.

We are currently in phase I of II of developing a civilian WBB which, to our knowledge, would be the first civilian WBB in the USA. The project would allow for rapid screening of donated LTOWB in a standard FDA-approved pre-screened donors from our Heroes in Arms program and subsequently allow for direct transfusion in the site of need during an MCI. A small sample of the blood would be kept from each donor for retrospective analysis to track any potentially transmissible diseases. After implementation of the questionnaire already used for the

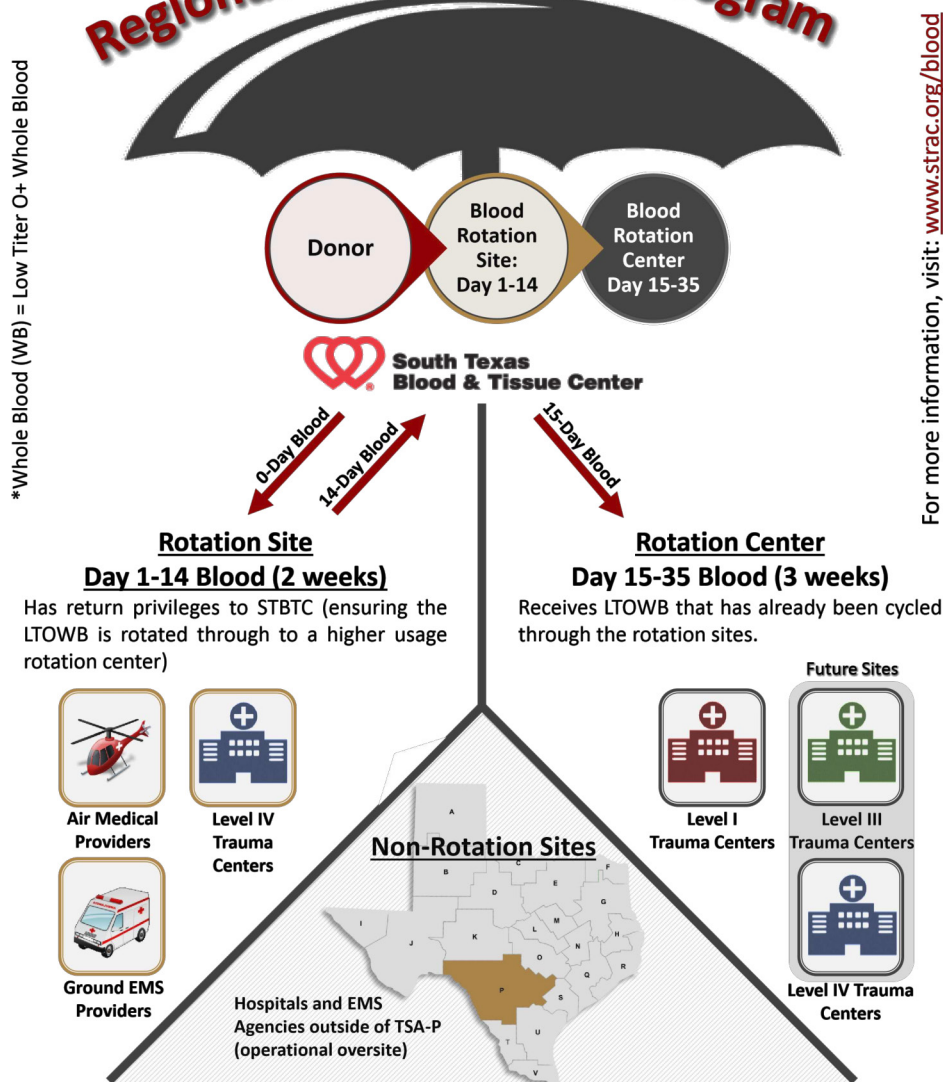


Figure 2 STRAC Regional Whole Blood Program Rotation Process. LTOWB, low titer type-O whole blood; STBTC, South Texas Blood and Tissue Center.

donors, phase I includes the development of the rapid screening process to test for ABO/Rh status and rapid viral sampling. Next, the sensitivity and specificity of the rapid tests will be determined. Phase II will include formalizing hospital, blood bank, and system-wide protocols, informing the public regarding the program and enrolling participants who could be called on in the event of an MCI. This would allow donors to arrive to donation sites throughout the city, and blood can flow essentially straight from donor to patient in a timely manner when major need arises. Were it needed to be activated prior to completion of phase II, the program is sufficiently safe and would be executed without the additional rapid testing in order to save lives.

CONCLUSION

Planning ahead for critical blood shortage related to casualty surge in an MCI can be accomplished in a local-regional manner, in

a safe and just in time fashion which will save lives when needs are greatest and blood supply is insufficient.

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