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SUPPLEMENT ARTICLE

TRANSFUSION

Civilian walking blood bank emergency preparedness plan

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Abstract

Background: The current global pandemic has created unprecedented challenges in the blood supply network. Given the recent shortages, there must be a civilian plan for massively bleeding patients when there are no blood products on the shelf. Recognizing that the time to death in bleeding patients is less than 2 h, timely resupply from unaffected locations is not possible. One solution is to transfuse emergency untested whole blood (EUWB), similar to the extensive military experience fine-tuned over the last 19 years. While this concept is anathema in current civilian transfusion practice, it seems prudent to have a vetted plan in place.

Methods and Materials: During the early stages of the 2020 global pandemic, a multidisciplinary and international group of clinicians with broad experience in transfusion medicine communicated routinely. The result is a planning document that provides both background information and a high-level guide on how to emergently deliver EUWB for patients who would otherwise die of hemorrhage.

Results and Conclusions: Similar plans have been utilized in remote locations, both on the battlefield and in civilian practice. The proposed recommendations are designed to provide high-level guidance for experienced blood bankers, transfusion experts, clinicians, and health authorities. Like with all emergency preparedness, it is always better to have a well-thought-out and trained plan in place, rather than trying to develop a hasty plan in the midst of a disaster. We need to prevent the potential for empty shelves and bleeding patients dying for lack of blood.

KEYWORDS
emergency, transfusion, walking blood bank, whole blood

1 | INTRODUCTION

The term "walking blood bank" (WBB) describes a setting where whole blood (WB) is drawn from donors who have been screened for their blood types and tested for pathogens on previous donations and the WB is transfused without further testing.[1–4] Conversely, transfusing blood from a donor who has not undergone the currently accepted screens for pathogens before the products are issued has also been described. These donors might have undergone rapid pathogen screening, or not at all, depending on the circumstances. For clarity, we define both of the latter products as emergency untested whole blood (EUWB). This process is not FDA-approved for civilian transfusion and is thus distinctly different from the FDA-approved, fully screened, low-titer group O whole blood (LTOWB), or ABO-specific whole blood, in current use in multiple countries, including the United States.[5] The WBB approach is implemented only in dire circumstances when standard FDA-approved blood component therapy is unavailable due to a myriad of logistical reasons. From WWI until the middle of the Vietnam War, WB was the backbone of hemorrhagic shock resuscitation.[6,7] Over the last 19 years, the US military has transfused more than 10,000 units of WB in Iraq and Afghanistan (both FDA-compliant, fully screened

LTOWB and noncompliant fresh WB), generating significant current best practice experience.[8–15] This 19-year experience has resulted in WB being described as the resuscitation fluid of choice for casualties in hemorrhagic shock.[11–15] Leveraging this wartime experience, LTOWB is in current use in more than 35 trauma centers across the United States.[16]

Given the current measures to decrease blood utilization (including canceling elective surgery), and willingness of donors to respond in emergencies and specifically the global COVID-19 pandemic, it is possible that the current adequate supply of blood products on the shelf will be sustained throughout the prolonged pandemic.[17–21] However, as the pandemic continues and supply chains are challenged, it is within the realm of possibility that hospital blood banks could be depleted without the possibility of resupply (Figure 1).[19–22] As described by Zimrin and Hess in 2007, pandemics can disrupt the fragile blood supply chain at many levels, including reagents, bags, personnel protective equipment, refrigerated shipping, restricted travel considerations, and all levels of personnel or donor availability.[19] A recent National Academies of Sciences, Engineering, and Medicine report describes the fragile nature of the just-in-time supply chain and how any national/international crises could disrupt the chain at many levels, requiring alterations in the standard of care.[20] They describe the vulnerability of current supply chain networks, which are optimized for maximum efficiency. While efficiency is desirable during routine practice, the deeply interdependent technological systems present multiple opportunities for single points of failures. The potential for cascading effects of supply chain failures during a crisis is substantial and could be catastrophic.

Protection of the blood supply during a pandemic or major disaster event requires planning for a steady stream of donors, understanding blood product requirements, donor center and transfusion service personnel security, assurance of access to supplies and reagents, maintenance of equipment and facilities, and assurance of the continuity of management.[22] If (or when) these protections fail, reverting to a non-FDA-approved WBB program may be the only option for blood collection centers or clinical transfusion services to provide a blood product for patients with severe, acute blood loss or other causes of life-threatening anemia, coagulopathy, or thrombocytopenia. Recognizing that the median time to death in massively bleeding patients is under 2 h, resupply from remote unaffected locations will likely not be beneficial.[23] Leveraging the extensive military experience with EUWB would continue until the interruption of the supply chain is resolved and FDA-approved products can be produced again. It is likely that the current extraordinary efforts by the entire medical and blood transfusion communities will prevent this from happening during this particular pandemic. While this concept is anathema to current civilian practice, given the current worldwide crisis it seems prudent to have a vetted plan in place for this possibility, however remote it seems. Our colleagues in San Antonio, Texas, are finalizing their planning; the Royal Caribbean Cruise liners have long utilized such a policy; and the transfusion authorities in Norway have already instituted such a plan and have activated it for several civilian emergencies.[2,4,24–30]

It is absolutely critical that the use of fresh EUWB described in this plan will be used only for patients with life-threatening bleeding, severe life-threatening anemia, or potentially profound thrombocytopenia. This is defined as a patient who is rapidly and severely bleeding where RBCs, plasma, and platelets are indicated, or anemia so severe as to cause significant signs of cardiovascular stress, or end-organ hypoxemia, and the patient is at risk of imminent death. EUWB would not be indicated

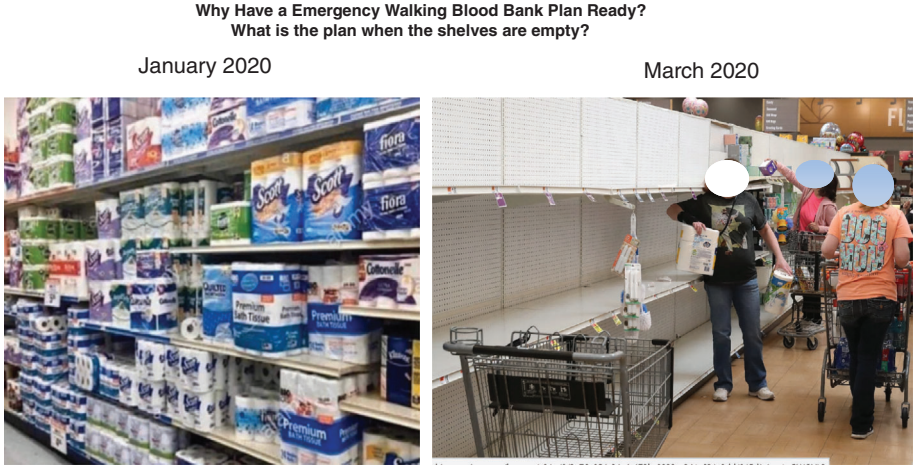

FIGURE 1 Why have an emergency walking blood bank plan ready? What is the plan when the shelves are empty?

for any prophylactic transfusion or to treat mild to moderate bleeding.

Innovative approaches are being adopted to enhance the blood supply and resuscitations. These initiatives include the use of group A thawed plasma, LTOWB, extended-shelf-life cold-stored platelets, as well as extending the shelf-life of current products. However, these approaches or products will not be sufficient if the fragile blood collection and testing system breaks down during the current COVID-19 crisis or future devastating events. While some may consider such contingency planning to be radical, it is simply prudent to have a nationwide plan for supplies and procedures that can be executed at the local level. The approach described below has been developed with input and consensus of civilian, military, and government experts and reviewed by a multidisciplinary group of military and civilian authorities. As an example, this plan could be distributed via the AABB Disaster Task Force (AABB DTF) and existing national blood communication systems to each donor center, blood bank, and hospital and modified as needed based on the unique resources available in each region. It is fully anticipated that local implementation of these high-level guidelines would be modified to meet local regional-specific requirements and emphasized that not all contingences can be fully described. Implementation will require evaluation and approval by a multidisciplinary group of medical experts, including guidance by local medical ethicists and appropriate public health authorities, as well as public engagement whenever possible.

Fully infectious-disease-tested ABO-type specific whole blood and LTOWB are FDA-licensed products and the AABB standards allow for the transfusion of ABO-type specific WB and LTOWB. LTOWB transfusion is becoming more common, albeit without randomized studies documenting efficacy.[2,16,24–32] However, supply chain issues may complicate timely infectious disease testing. Emergency use of the WBB would not allow for the time (typically requiring 12–24 h after donation) required for complete infectious disease testing. Lack of complete viral testing will be seen by prescribers and patients as a significant safety concern. However, the prevalence among first-time donors of HIV, HCV, and HBV in more than 40 million blood donors between 2007 and 2016 was 1.65, 11.47, and 5.85 per 100,000 donations, respectively.[33] The very low risk of communicable disease transmission, especially with repeat donors, will need to be balanced with the >20% risk of death within 3 h of injury due to acute, severe blood loss.[23,34] This dilemma is similar to the challenges of WB use and triage in a battlefield setting.[34] In a clinical setting where patients are dying of acute blood loss, in which transfusion would be of great benefit, transfusing (minimally or untested for infectious diseases, non-leucocyte-reduced or titered) EUWB from donors who have safely donated in the past 6 months seems reasonable. To decrease risk, an abbreviated donor history questionnaire (aDHQ) should be utilized for this emergency event.[3] Further risk mitigation by using approved rapid diagnostic tests (HIV, HCV, and HBV) in a point-of-care (POC) manner should be utilized if available.[35] These tests are not FDA-cleared for this specific purpose, but are widely used in many countries, as well as by the US military while in a deployed setting.[34]

Implementation of such a plan for a civilian WBB may be expected in two scenarios. First is the mass casualty situation where an already stressed blood component system is rapidly overwhelmed (Figure 2). Use of WBB in this situation will be an emergent and episodic situation. A more nuanced, and perhaps more ominous, situation arises if there are no products on the shelf secondary to a massive national-level disruption of the supply chain from a prolonged pandemic crisis (Figure 3). This latter situation may be more prolonged and require sustained use of nonapproved products. Ultimately, the decision to transfuse EUWB will rest with the treating physician in consultation with the patient and/or family, understanding the balance of time to transfusion in patients with life-threatening bleeding versus obtaining individual informed consent. Use of the WBB and EUWB will become necessary until the supply chain is re-established and FDA-compliant blood product resupply can be restored.

In the midst of a pandemic-induced shortage, a movement away from standard accepted blood banking and transfusing practices must be justified by the intention to maximize benefits to individuals in need of life-saving blood products while minimizing the risks as much as possible (e.g., from transfusion-transmitted infections and hemolytic reactions). That is, the central driving concern would be a favorable benefit versus risk calculation. This should be based on scientific data, on empiric information, and on prior experience with other pandemics as well as military and civilian emergency need for blood products during mass casualty situations that overwhelm the available supply.

While national-level guidance for this type of intervention is useful, local regional health experts should be the appropriate approving authority. The promulgated guidelines for approaching a severe blood product and supply chain shortage must be based on the principles of justice.[36,37] National and local policies geared toward efficiency and expediency (getting the needed products to dying patients in the most time-sensitive manner) should ensure equal access of comparably ill patients to medically necessary blood products. To help ensure that

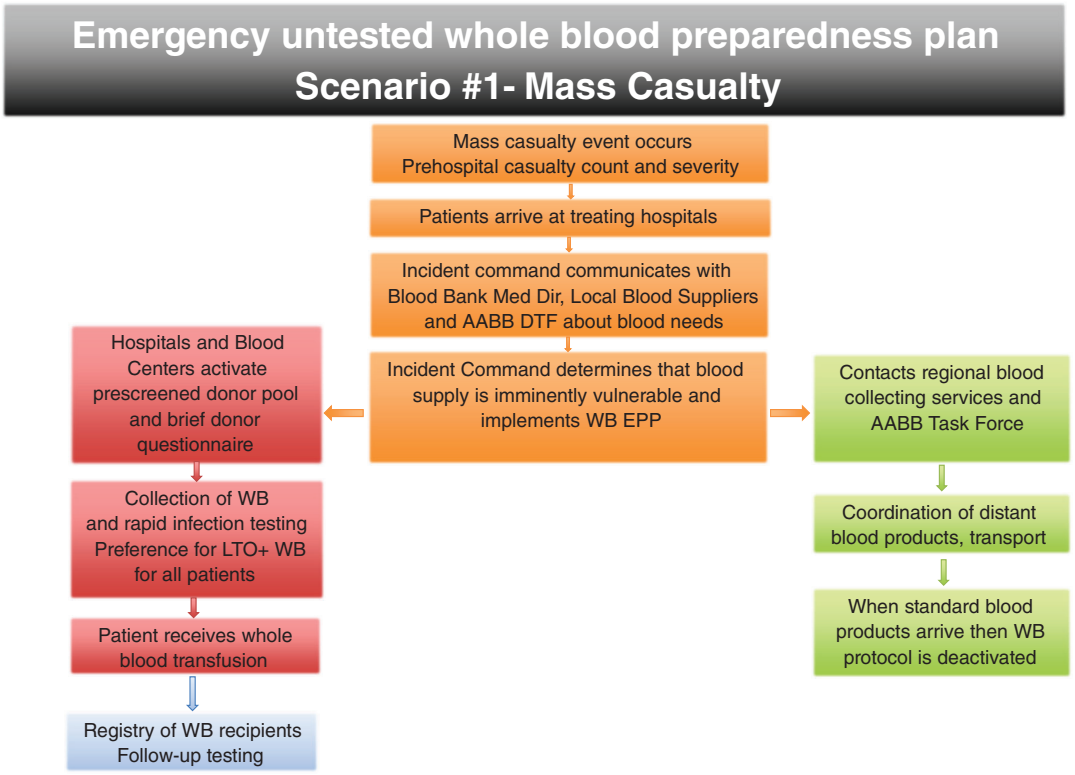

FIGURE 2 Emergency untested whole blood preparedness plan scenario #1: mass casualty

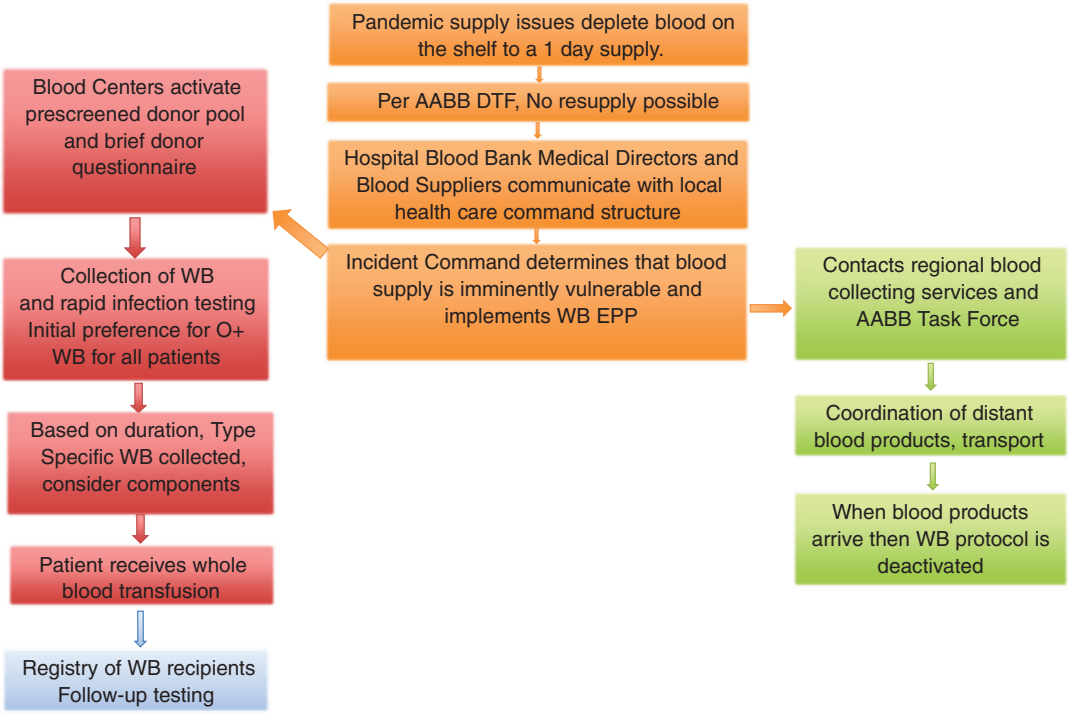

FIGURE 3 Emergency untested whole blood preparedness plan scenario #2: sustained pandemic

resource allocations are distributed in an equitable manner, this process must be transparent, involving relevant federal agencies, and the appropriate state, regional, and local emergency preparedness and medical delivery services. Ultimately, the decision to transfuse nonstandard blood products will rest with the treating physician in consultation with the patient and/or family (understanding the relevant time constraints regarding consent). Moreover, the process by which the governing guidelines have been developed must involve the public. Public engagement should have several goals, including the following:

- Define why standard transfusion practices are not currently possible.
- Explain what the changes to standard practice are and what the associated risks may be.
- Explain the evidence supporting the recommended changes in a manner that is understandable to laypeople.
- Provide an opportunity for public input.
- Provide information to potential donors and recipients.
- Develop and maintain public trust and confidence in the process by which the national and local guidelines were established.

The following recommendations are meant to be high-level guidance for experienced blood bankers, transfusion experts, and bedside clinicians and most certainly will be modified based on local circumstances if and when they are implemented. Why have a plan ready? Like with all emergency preparedness, it is always better to have a well-thought-out and trained plan in place, rather than trying to develop a hasty plan in the midst of a disaster. We need to prevent the potential for empty shelves and bleeding patients dying for lack of blood when the military has a fine-tuned plan for EUWB over the last 19 years.

2 | RECOMMENDATIONS

1. Emergency WBB supply plan activation and deactivation criteria
   a. Activation: The emergency WBB supply plan should be activated in the following scenarios, and the amounts of EUWB collected will depend on the local population served.
      i. Casualty event where the local blood supply is exhausted or projected to be exhausted within several hours (e.g., within 6 h) and local or regional resupply is not possible. In this scenario, WBB can be acquired by blood collection centers or hospitals that have been educated and trained in the process of collecting WB under emergency conditions (Figure 2).
      ii. During a prolonged pandemic when the local blood supply is approaching zero and the on-the-shelf supply is 1 day or smaller of platelets, plasma, or RBCs, with ongoing need for products and the inability to schedule resupply. Coordination with the AABB Disaster Task Force is essential. Standard blood products will always be used prior to any WB collected by the WBB under emergency circumstances. Only when all fully tested blood products are exhausted will emergency-release, nonstandard WB be used. For this scenario, EUWB should optimally be collected at licensed blood collection centers (industry- or hospital-based) (Figure 3).
   b. Deactivation: The emergency WBB plan will be deactivated by the local health authority upon the recommendation of the transfusion Medical Director in the following scenarios:
      i. Scenario 1 (Figure 2). The collection of EUWB will be terminated when an adequate supply of fully tested blood products arrives from an outside region or has been drawn and fully tested by the blood center. Each region will need to define their own adequate supply (e.g., 1–2 days of fully FDA-compliant blood products).
      ii. Scenario 2 (Figure 3). The collection of EUWB will be terminated when an adequate supply of fully tested blood products arrives from an outside region or have been drawn and fully tested by the blood center. Each region will need to define their own adequate supply (e.g., 1–2 days of fully FDA-compliant blood products).
2. Use of emergency untested WB: It is absolutely critical that the use of EUWB described in this plan will be used only for patients with life-threatening bleeding or severe life-threatening anemia or thrombocytopenia who would otherwise be predicted to die if they are not transfused. This is defined as a patient who is rapidly and severely bleeding where RBCs, plasma, and platelets are indicated or anemia so severe as to be causing significant signs of cardiovascular stress or end-organ hypoxemia putting the patient at significant risk of imminent death. EUWB will not be indicated for any prophylactic transfusion or mild to moderate bleeding.

3. A regional/local plan for a WBB. Each region will differ on specifics, but general principles will apply.
   a. It will be important to periodically test this process before it is actually needed. Established donor centers, blood banks, and hospitals do not usually have a plan in place, including IT management systems and all the supplies, to institute a WBB.
   b. Each local blood center and participating hospital should identify the location of the drive(s), personnel support (by position) to assist with donor screening and phlebotomy, etc. Public notification of "WBB donor centers" will be important. There are only a limited number of "medical technologists/phlebotomists," so other non-traditional personnel may need to be trained to assist if not needed for patient care.
   c. If available, a donor van placed in the parking lot of the hospital (or other appropriate location) will be useful. If not close to hospitals, it might be ideal for hospitals to set up donor centers within their facilities or identify several sites to be set up as emergency collection locations. In a pandemic, donor and healthcare worker safety must be considered, so all applicable safety measures should be practiced.
   d. All required standard operating procedures, forms, etc. should be placed in a designated location.
   e. Plan for standard computer data entry, understanding that this procedure may be impossible and require paper documents.
   f. Plan for data entry by non-lab-experienced personnel.
   g. Plan for a designated number of supplies/donor kits, including training kits.
   h. Plan for a regional supply rotation schedule to prevent wastage as well as for the number of EUWB collection and testing kits to be used for training.
   i. Plan for sending donor samples for standard transfusion-transmissible diseases (TTD) testing as soon as possible. Plan for notification to hospital if the donor tests positive.
4. What is a suitable titer level for anti-A and/or -B in WB collected at a WBB? Up to 256 is acceptable and has been used by the Department of Defense (DoD) for 50 years. Given the time-sensitive situation and that truly high titers are unusual, it is likely that titering the EUWB before issue may not be possible and it is acceptable for the Medical Director to waive this requirement.
5. Plan for LTOWB, type OWB, or type-specific?
   a. The WB donors and collections should clearly target group O universal donor whole blood (likely nontitered) for widespread use in settings where patients need transfusions urgently and before the recipient's ABO blood grouping is obtained (this is a critical need in major disasters). In a time-sensitive emergency, where administrative errors are more likely to occur, Group O WB is the preferred transfusion product.
   b. There will likely be an ongoing need for WB in the setting of disasters that are on a longer timeline, such as a pandemic. Hospitals will be enabled over a longer term incident to have access to validated ABO group results in patients. It might be necessary to expand the donor pool and collections to all blood types.
   c. Rapid ABO typing options for recipients should be explored, validated, and implemented when this capability is needed.
   d. When transitioning patients to type-specific EUWB for recipients who have known blood types, collecting largely group O and A WB donors will likely suffice for most recipients (AB and B donors are an added plus).
      i. Low titer Group O WB donor: suitable recipients are O, A, AB, B;
      ii. High titer Group O WB donor: suitable recipients are O;
      iii. Group A RBC donor: suitable recipients are A, AB;
      iv. Group A plasma donor: suitable recipients are O, A, AB, B;
      v. The great majority of the donor population in the United States is composed of groups A and O donors. By collecting type-specific EUWB, and using the group A WB donor for the A recipients, then the group O WB donors could support O, AB, and B recipients.
6. O negative or positive? Rh negative (Rh–) products are very limited under normal circumstances, and given the low risk of alloimmunization and the subsequent potential for hemolytic disease of the fetus and newborn when adopting a WBB approach, it is acceptable to transfuse RhD+ products to RhD– or RhD type unknown women of child-bearing age, after waiver by the Medical Director.[38]
7. Leukocyte reduction? Continue with local standard practice and supplies, knowing that not all centers utilize this approach. Leucocyte reduction, while standard in many countries, is not universally utilized in WB transfusion, and recent data suggest it may impair

PRE-SCREEN / EMERGENCY WHOLE BLOOD DONATION RECORD

Form is only to be used for pre-screening or collecting donors in support of contingency / deployed operations.

DONATION IDENTIFICATION NUMBER (DIN)

(Use Donor SSN if ISBT # Not Available)

TODAY'S DATE	NAME (Last, First, Middle Initial)	RANK/RATE	USA USAF USN USMC CIV	SSN: DoD ID:
UNIT	UNIT LOCATION (Base and State)	AOR BASE & TENT# (if deployed)	DOB (DDMMMYYYY)	SEX: M F ABO/Rh (Blood Type)
CURRENT MAILING ADDRESS		EMAIL ADDRESS		BEST CONTACT PHONE NUMBER

Group A Questions (ALL DONORS Must Complete)

1	Have you read and do you understand the educational materials provided to you?	Y	N	5	Have you ever received money, drugs, or other payment for sex?	Y	N
2	Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?	Y	N	6	Have you ever had cancer, heart problems, bleeding conditions, or lung disease?	Y	N
3	Have you taken any of the medications listed on the back of this form within the timeframes shown? If Yes, write medications here: _____	Y	N	7	Have you ever had hepatitis, or have you ever taken medication for treatment or exposure to hepatitis?	Y	N
4	Have you ever had a positive test for the HIV/AIDS virus?	Y	N	8	Have you ever had Malaria, Chagas or Babesiosis?	Y	N

Interviewer:** Document review and eligibility below for walking blood bank (WBB) and/or low titer group O whole blood (LTOWB) donor program.

DONORS: If you are being **prescreened** for a WBB or LTOWB program, **STOP!!** Answer no more questions and sign at the bottom.
If you are here to donate a unit of blood, proceed to **Group B Supplemental Questions** and then sign at the bottom.

Group A responses acceptable (all no except Q1)? Y N ***Interviewer (initials):	All disease tests negative? Y N	Eligible for WBB? Y N	Titer Result (If group O): _____ (accept if < 256)	Eligible for LTOWB? Y N	Approving Official	Low Titer ID Issued? Y N NA

Comments:

Group B Supplemental Questions (Complete if Donating a Unit of Blood Today)

9	Are you feeling healthy and well today?	Y	N	18	In the past 12 months, have you lived with or had sex with a person who has hepatitis?	Y	N
10	Female donors: Have you ever been pregnant or are you pregnant now?	Y	N	19	In the past 12 months, have you had a transplant (such as organ, tissue, or bone marrow) or graft (such as bone or skin)?	Y	N
11	Female donors: Have you had sexual contact with a male who had sexual contact with another male in the past 12 months?	Y	N	20	In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	Y	N
12	Male donors: In the past 12 months, have you had sexual contact with another male?	Y	N	21	In the past 12 months, have you come into contact with someone else's blood?	Y	N
13	Are you currently taking malaria prophylaxis?	Y	N	22	In the past 12 months, have you had an accidental needle-stick?	Y	N
14	Are you currently taking any medications for an infection?	Y	N	23	In the past 12 months, have you had a blood transfusion?	Y	N
15	Have you had physical contact with someone who was vaccinated for smallpox in the past 8 weeks?	Y	N	24	In the past 12 months, have you had sexual contact with anyone who takes money or drugs or other payment for sex?	Y	N
16	In the past 48 hours, have you taken aspirin or anything that has aspirin in it?	Y	N	25	In the past 12 months, have you had or been treated for syphilis or gonorrhea?	Y	N
17	In the past 8 weeks, have you donated blood, platelets, or plasma?	Y	N	26	In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	Y	N

Comments:

Today's Date:	Temperature: _____°F/°C (≤ 99.5°F/37.5°C)	Blood Pressure: _____/_____ Systolic: 90-180 Diastolic: 50-100	Pulse: _____ (50-100 bpm)	Hemoglobin: _____ Male: ≥ 13.0 g/dL Female: ≥12.5 g/dL	Weight: _____ (≥ 110 pounds/50kg)	Vital Signs Tech:

Does Donor Qualify? Y N ***Reviewer (initials):	Phlebotomist	Start Time	Stop Time (<15 mins)	Bag Manufacturer	Lot #	Expiration Date:	Segment #

I verify that I have answered the questions honestly, I had an opportunity to ask questions, I consent to donating blood today, and I feel my blood is safe to be transfused. If I am donating a unit of whole blood today, my blood will **NOT** be tested for viral diseases prior to transfusion due to the emergency situation. If for any reason I feel that my blood may not be safe, I will not donate today.

_____

Donor's Signature ***Date***

ASBP 572-EWB (Emergency Whole Blood), 5 Apr 2018

Check Deferral Status (initials):_____ Date: _____ Entered into Blood Management System by (initials)_____ Date:_____

FIGURE 4 Abbreviated donor screening questionnaire from the DoD armed services blood program

DONOR EDUCATIONAL MATERIAL

Blood donation is a voluntary process requiring the collection of approximately 450-500 mL of blood. The usual collection time ranges from 5 to 10 minutes. Complications at the venipuncture site may include, but are not limited to: discomfort, bruising, swelling, or infection. Other complications could occur during or after your donation such as: fatigue, light-headedness, dizziness, nausea, vomiting, and/or fainting. On very rare occasions, a more severe reaction may occur.

MEDICATION LIST: Donors **SHOULD NOT** discontinue medications prescribed by their physician in order to donate blood. Certain medications in your system can cause harm to some patients if your blood is transfused. If your last dose of the following medications was taken within the timeframe listed, you should not donate today nor should you participate in a walking blood bank program because the medication has not cleared from your system.

Prescreen or Donating Blood Today:

Erivedge, Odomzo	Soriatane	Bovine Insulin, Human Growth Hormone, Tegison
2 years	3 years	**EVER** in your life

Donating Blood Today (must screen donor for drugs below AND list above if donating whole blood):

Eliquis, Feldene, Fragmin, Lovenox, Pradaxa, Savaysa, Xarelto		Arixtra, Brilinta, Coumadin, Effient, LMW Heparin, Jantoven, Warfilone	
2 days		7 days	
Plavix, Ticlid, Zontivity	Absorica, Accutane, Amnesteem, Claravis, Myorisan, Propecia, Proscar, Sotret, Zenatane	Avodart, Jalyn	Experimental Meds/Vaccines
14 days	1 month	6 months	1 year

Your signature on the other side of this form acknowledges that you understand the questions and this educational material and that you agree to not donate any blood products if you are at risk of transmitting Human Immunodeficiency Virus (HIV) or any other virus. We know that you would not donate unless you think your blood is safe. However, in order for us to assess all risks that may affect you or a patient receiving a transfusion, it is essential that you answer each question completely and accurately on the other side of this form. If you do not understand a question, ask a staff member. All information you provide is confidential. It is critical that you alert your unit provider or medic if any of your responses change or if you have any concerns about the safety of your blood. This will facilitate notification and follow up testing for the recipient if needed.

Your blood will be tested for several types of viral markers including Hepatitis B, Hepatitis C, HIV, syphilis and other infections. You will be notified about any positive test result which may disqualify you from donating in the future, and your name will be entered onto a list of permanently deferred donors. If testing does not occur (due to specimen acceptability) or if testing results are not clearly negative or positive, your name may be placed on a deferral list without you being informed until the results are further clarified. For active duty personnel and reservists, positive screening and confirmatory results will be forwarded to appropriate medical personnel for further evaluation and "fitness for duty" determination (if required).

HIGH RISK BEHAVIORS:

Certain diseases such as HIV/AIDS and hepatitis can be spread through sexual contact OR by sharing drug needles/syringes. These viruses can enter your blood stream and can be transmitted to another person who is transfused with your blood, plasma, or platelets. Sexual contact includes: Vaginal contact (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), and/or anal sex (contact between penis and anus). **YOUR BLOOD CAN TRANSMIT DISEASES,** including HIV/AIDS, even if you feel well and all your tests are normal. This is because even the best tests cannot detect the virus for a period of time after you are infected.

DO NOT DONATE IF YOU:

- Have AIDS or have ever had a positive HIV test
- Have ever used needles to take any drugs not prescribed by your doctor
- Are a male who has had sexual contact with another male in the past 12 months
- Have ever taken money, drugs or other payment for sex
- Have had sexual contact in the past 12 months with anyone described above
- Have had syphilis or gonorrhea in the past 12 months
- Have been in juvenile detention, lockup, jail or prison for more than 72 consecutive hours in the past 12 months

DO NOT DONATE TO GET A TEST! If you think you may be at risk for HIV/AIDS or any other infection, do not donate simply to get a test. See your medical provider to obtain an HIV/AIDS test. The following symptoms can be present before an HIV test turns positive: fever, enlarged lymph glands, sore throat, and/or rash.

NOTIFY YOUR UNIT MEDIC OR UNIT PROVIDER IF:

- Anything changes that would cause a different response to a question
- If you think your blood may not be safe for another person to receive
- If you become sick within 14 days after donating a unit of blood

THANK YOU FOR DONATING BLOOD!

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FIGURE 4 (Continued)

platelet function and clinical outcome.[39] In a time- and resource-limited situation, it is likely and acceptable for the Medical Director to waive this requirement.

8. TRALI mitigation. Utilizing only male donors or females without a pregnancy history to mitigate transfusion-related acute lung injury (TRALI) has

been successful. While important, the small risk of TRALI is outweighed by the much larger risk of dying from hemorrhagic shock if blood is not available.[40,41] When the emergency WBB plan is instituted, the Medical Director could waive this restriction if low-TRALI-risk donors are not available.

9. Donor screening and collection. Even in an emergency situation, donor screening and determination of eligibility is extremely important.
   a. Consider using the abbreviated emergency WB donor screening questionnaire from the DoD Armed Services Blood program, modified as needed for local civilian requirements (Figure 4) or a civilian version, (reference #3).
   b. Recommend that the hospital and blood center plans be shared with (but not limited to) the following community partners: local and regional health departments and EMS/fire/police personnel.
   c. It will be optimal to collect blood from donors who have been screened or have donated within the last 3–6 months; however, a priority/list should be developed to determine the order in which donors will be utilized during emergency events/situations.
   d. All donors who have been screened or have previously donated should be made aware of the program and the potential to respond to public or personal calls to report for donation, especially those who are group O. For planning purposes, this could be incorporated now into the required post-donation instructions and materials.
   e. In addition to the reliable blood donor population, a preplanned donor questionnaire and infectious disease screening program among hospital and EMS/fire/police personnel should be initiated. They are immediately available and will donate in an emergency. In the military special-operations soldiers, WB donation has been shown to not adversely affect their job performance.[42]
   f. Hospital visitors and other "never-been-screened" donors would be last in the priority/listing but should be considered if necessary and undergo a documented rapid screening process.
   g. Recommend that an aDHQ (Figure 4) and process be utilized for use during an emergency event. The following steps are recommended:
      i. Instruct the donor to complete the approved aDHQ demographic information, answer the questions, and sign the form.
      ii. A qualified interviewer should review the card, complete the abbreviated donor interview process, and ensure that the donor is not currently deferred.
      iii. The donor's temperature and blood pressure should be taken if possible and recorded on the aDHQ.
      iv. Collection bags should labeled with the donor identification (per locally approved procedure).
   h. Donor phlebotomy should be performed by personnel educated and trained in the procedure.
   i. Donor phlebotomy should be completed in accordance with locally approved procedures. Procedures should include guidance for collections if standard donor equipment is not available such as donor beds and scales.
   j. Donor sample tubes should be processed for the retrospective completion of TTD testing.
   k. Donated units should be labeled in the standard manner if possible, but at least with the donor ABO/Rh, date of collection, time of collection, and phlebotomist's initials. It is essential that a system be created to ensure traceability from donor to patient in case of positive results in retrospective TTD testing.
   l. All results should be captured on locally approved forms and standard registries, to be entered into the designated Blood Enterprise Computer System (BECS) when possible.
   m. Units collected at a WBB drive should be stored, shipped/transported, and released per locally approved procedures.
10. Documentation. If the WBB program is conducted in a donor center, documentation can be done via the established procedures. However, given the nonstandard product being utilized, some electronic systems may not "accept/allow" this transfusion. Always have donor cards as back-up documentation especially for those locations that do not have a computer. Centers must have a plan for paper documentation if technology fails.
    a. The donor screening and collection should be documented on the locally approved aDHQ for emergency collections.
    b. The collection team should have a method to check the donor deferral roster during the process, and that check should be documented.
    c. The processing of donor units, rapid testing, and samples should be documented on the locally approved forms.
    d. The transportation of collected units, donor samples, and completed forms should be done per locally approved procedures.
    e. Documentation in the BECS should be completed as required. Locally approved procedures should

outline which system will be utilized: BECS/paper/combination of both.

11. Rapid ABO typing and infectious disease testing. Acquisition of the rapid diagnostic tests for ABO type and HIV, HBV, and HCV that can accomplished in a POC manner is recommended. This process will likely not be familiar to the testing personnel, so acquisition ahead of time and practice is recommended. This approach should be used as widely and as often as possible during the WBB drive. If these POC infectious disease tests are not available, untested WB can be transfused when approved by the Medical Director. Appropriate samples should be collected at the time of EUWB collection, frozen, and conventional infectious disease testing completed at a later time.
    a. Collected donor units and sample tubes should be taken to the designated donor processing area. The following representative rapid testing should be completed to the greatest extent possible and results should be documented per locally approved procedure. These tests described below is not an exhaustive list and is presented only as examples. They are not as accurate as those performed for FDA-approved blood products and are not used in the United States to test blood products prior to release. However, they are used as rapid screening tests and are 98%–99% accurate. The following examples are only representative for some of the rapid tests that are available.
        i. Eldon Cards for rapid ABO typing; https://www.eldoncard.com/
        ii. HIV OraQuick ADVANCE Rapid HIV Test;
            1. https://www.orasure.com/products-infectious/products-infectious-oraquick.asp
        iii. HCV OraQuick ADVANCE Rapid HCV Test;
            1. https://www.orasure.com/products-infectious/products-infectious-oraquick-hcv.asp
        iv. HBsAg Test
            1. https://www.alere.com/en/home/product-details/determine-hbsag-2.html
    b. If rapid infectious disease testing cards are not available, it is recommended that previously tested donors be utilized, starting with those who have safely donated most recently.
12. Storage and handling of EUWB. WB can be stored without agitation at 2–6°C for up to 21 days if collected in citrate phosphate dextrose solution and up to 35 days if collected in citrate phosphate dextrose adenine-1 solution. In scenario #2 (Figure 3), if components are produced from EUWB, they should be stored per AABB standards and FDA regulations and guidance.
    a. Cold-chain management and temperature monitoring should be accomplished according to standard procedures.
    b. Once standard, fully tested blood components are available again in adequate quantities, the EUWB units should probably be discarded.
13. Ethics. Given the unique circumstances, bioethics expertise has been integral to developing this guideline.
    a. Local ethics input should be obtained before the implementation phase of this process.
    b. Modification of the standard blood product consent process will be required with implementation of the nonstandard WBB program. As in any emergency situation, if time permits, patients (or much more likely their surrogate) will need to be informed prior to providing an EUWB transfusion. The informed consent should include a disclosure of the reasons for the deviation from standard blood products, the differences between standard practices, that EUWB is not tested to the standard level, that the only alternative to EUWB is not receiving it as it is the only product available, and the anticipated risks and benefits associated with EUWB.
    c. Utilize the ongoing accepted blood product registries and hospital performance improvement process to capture which patients receive EUWB and their outcomes, including potential seroconversion.
14. Site-specific issues
    a. Alert the community that the WBB program will be implemented.
        i. Cell numbers of previous donors, radio, TV, social media, hospital public address systems
    b. Large signs (A-frames) that can be positioned to assist with the flow of donors to the designated areas.
    c. Caring for donors
        i. Food, drinks, etc.
        ii. Plans to deal with donor reactions.
    d. Medical Director: Pre-appoint a designate in case the blood bank physician cannot make immediate decisions
    e. Location of processing the units: at donation site or back in the lab
    f. Labeling of nonstandard emergency-release WB
    g. Production of nonstandard blood components from emergency WB will be dependent on the duration of blood shortage and patient requirements.

CONFLICT OF INTEREST

PCS is a consultant for Hemanext, Cerus, Entegrion, and Secure Transfusion Services. JOJ is a consultant for CSL Behring. MAS is a consultant for Haemonetics and CSL Behring. KRW is a LTC in the U.S. Army Reserve MC. He has several technologies and patents through the University of Michigan regarding hemostasis. He receives research funding from the Department of Defense. MY has received honoraria from Terumo, Haemonetics, Cook Biomedical, and Grifols. He has received paid travel from Terumo and Cerus. He is on the advisory boards for New Health Sciences, Aktivax, Macopharma, Octapharma, and Verax Biomedical. JBH is a co-founder and on the Board of Directors of Decisio Health, on the Board of Directors of QinFlow and Zibrio, a Co-inventor of the Junctional Emergency Tourniquet Tool, an adviser to CSL, Safeguard, Arsenal Medical, Cellphire, Spectrum, and PotentiaMetrics. All other authors have disclosed no conflicts of interest.

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