Field Operable Human to Human Blood Transfusion Meter

- **Provides faster response time for resuscitation of wounded soldiers.**
- **Reduces reliance on blood components that may not be in the right place at the right time.**
- **Delivers whole blood to patient without deleterious effects of anti-coagulants.**
- **Utilizes a "walking blood bank."**
- **Delivers precise blood volume from donor to patient at correct reinfusion rates.**
- **Simple, fast, and easy to use.**
- **This device will save lives.**

1. The purpose of this product

We have developed a working prototype of a simple handheld device to aid in transfusing whole blood from a donor to a wounded soldier to save lives. Because this method does not use an IV collection bag, our device 1) meters the volume of blood taken from the donor and 2) delivers whole blood to the patient at the correct reinfusion rate.

When a soldier is wounded, time is of the essence. Our device will:

- Enable resuscitation to start faster

- Provide the ability to deliver multiple units of whole blood from a walking blood bank

- Deliver whole blood to the patient without anti-coagulants, which are detrimental to patient outcomes

2. What is the transfusion procedure today, and what are the limits of current practice?

Quote from a medical professional: "*Resuscitation needs to begin within 36 minutes after an injury to improve outcomes, which is really hard to do. Right now, corpsmen carry blood bags*

that are preloaded with anticoagulant. When someone is injured, they must find a donor and fill a bag, which takes time, then hang the bag and let it drain into the patient, which takes more time, and the patient gets dosed with an anticoagulant while they're in hemorrhagic shock, which isn't good and has to be corrected by giving calcium replacement."

The current procedure requires filling an IV bag that contains anti-coagulants. Then infusing the patient from the IV bag. This two-step process costs valuable time in an emergency trauma situation. In addition, the IV collection bags contain anti-coagulants. Anti-coagulants are helpful when blood requires storage. However, infusing a wounded soldier with anti-coagulants can cause them to bleed out and die.

Coagulopathy (the inability for blood to clot) develops in 44% of all seriously injured patients and accounts for most deaths that occur in the first 24 hours of admission after trauma.[1] To combat coagulopathy, partially caused by the anti-coagulant, medical personnel must inject the patient with calcium or tranexamic acid and infuse the wounded soldier with blood components, fresh frozen plasma, packed red blood cells, and platelets in a 1:1:1 ratio. The combination of these blood components means the patient is virtually receiving "reconstituted whole blood."

Why go through the process of repairing the damage caused by anti-coagulants with blood components instead of transfusing fresh whole blood? Transfusing whole blood saves time and can save lives.

The excerpts below are from: **JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)** [2] Whole Blood Transfusion, this paper compares the use of fresh Whole Blood collected (FWB) on an emergency basis from a "Walking Blood Bank" (WBB) with Stored Whole Blood (SWB).

The clinical data comparing Whole blood (WB) to blood components have recently been reviewed.[6] Currently available clinical data indicate that use of WB to treat hemorrhage results in outcomes that are at least as favorable as those that can be expected with component therapy that includes RBCs, plasma, and platelets.

Severely injured combat casualties requiring transfusion have a significant mortality rate (16%) and have the greatest potential to benefit from early and appropriate transfusion strategies. A large retrospective cohort study of casualties requiring transfusions during Operations Iraqi Freedom (OIF) and Enduring Freedom (OEF) suggests a significant survival benefit for transfused casualties when RBCs, fresh frozen plasma, and platelets are transfused at a 1:1:1 ratio.[9] A recent randomized trial in civilian trauma patients demonstrated that a 1:1:1 transfusion ratio resulted in improved early hemostasis, though no statistically significant improvement in survival.[10] Two retrospective analyses in combat casualties comparing FWB to component therapy (which included platelets) have also been published. One study showed a potential survival benefit to the use of FWB during resuscitation of severe combat injuries, and the other showed FWB to be equivalent to component therapy.[11,12] These studies underscore the importance of providing all elements of whole blood (RBCs, plasma, and platelets) to severely bleeding patients and suggest that use of either WB or components in a 1:1:1 ratio for resuscitation of bleeding patients is acceptable; product choices can be guided by practical considerations.

It should be noted that the 1:1:1 ratio of blood components (platelets: plasma: RBC) recommended for damage control resuscitation does not faithfully reconstitute WB.

WB delivers all needed elements of blood in only one product, which only requires refrigeration for storage. In contrast, component therapy requires multiple products and storage modalities

(refrigeration, freezing and generally room temperature storage with agitation for platelets–though platelets can also be refrigerated), greatly increases workload and complexity for clinical teams.

When soldiers are wounded in battle, immediate transfusion may be required. Resuscitation must begin within 36 minutes to increase chances of a favorable outcome. The wounded soldier might not have access to an aid station where stored blood and blood components are available. Even when medical assistance is available, there are issues and complications dealing with stored blood components.

A report titled **Massive Blood Transfusion–Lessons from the Military**[3] states: *Due to difficulties related to packaging and thawing of the plasma in combat zones, delays can happen in being able to quickly administer a sufficient quantity of blood to trauma patients. The severe loss of blood and the inability to replenish it in a timely manner can create new problems for patients that may be life threatening.*

In a far forward military environment, the situation is even more dire. Thawing the thinly packaged FFP, which is stored at -20C, can cause ruptures in the plastic, creating delays in thawing other blood component units in the warmer. "Approximately 25 percent will experience a break in the bag as thawing occurs, rendering them unavailable for use," according to the study.

The current procedure requires a donor to fill an IV bag that contains anti-coagulants. Then the patient is infused from the IV bag. This two-step process takes valuable time. In addition, there are the debilitating effects related to anti-coagulants discussed above. If direct WB transfusion can be administered by corpsmen on the battlefield, lives can be saved.

It is believed that transfusing whole blood directly from donor to patient will result in getting urgently needed blood to the patient faster and without the complications created by anti-coagulants.

Our proposed device will reduce the waste of blood components supplies and enable the delivery of Fresh Whole Blood (FWB) where and when it is needed. The current methodology and practice results in huge amounts of waste.

A study entitled **Fresh Whole blood Transfusion: A Controversial Military Practice**[3] states:

Assuring the availability of conventional PRBC in a combat theater is the duty of the Armed Forces Blood Program and, in OIF specifically, the Southwest Asia Theater Blood Program. To meet this requirement, over 90,000 units of PRBC were sent to Iraq in the first year of the war; about 75,000 units during the first 10 months covered by the review above. Altogether, 1,697 of these units were used to treat US casualties for a usage rate of just over 2%. PRBC wastage rates are high, even for individual actively engaged units such as the 2nd Armored Cavalry Regiment (ACR) and 274th FST, where wastage was reported as 87% and 94%, respectively (personal communication).

High rates of RBC wastage have also been noted in the Korea, Vietnam, Bosnia, and Kosovo conflicts. Even though RBC were sent to these theaters in amounts 50 times in excess of use, local shortages occurred because small, mobile surgical units had limited carrying capacity and occasionally high demand. This inefficient use of resources is inevitable on the battlefield because of the episodic nature of combat injury and the necessity of forward-deployed medical units to be prepared at all times to receive casualties.

Further contributing to wastage, units of FFP frozen for transport at very low temperatures routinely break upon thawing, resulting in a 25% to 50% rate of wastage.

3. What is new in our approach and why do we believe it will be successful?

Severely injured combat casualties requiring transfusion have a mortality rate of 16% and have the greatest potential to benefit from early and appropriate transfusion strategies. We believe that human to human blood transfusions will significantly reduce the mortality rate of wounded soldiers.

The British obstetrician, James Blundell, performed the first human-to-human blood transfusion, in 1818. While Human to Human transfusion is not the accepted practice today, medical practitioners are starting to change their thinking.

A device that enables Human to Human transfusions for emergency situations that safely and accurately transfers whole blood from a donor to a wounded soldier would save lives.

Our proposed device is simple and easy to use. The field operable Human to Human transfusion meter delivers whole blood to the patient at a rate that matches the reinfusion rate of 46.2 mL/min for the FAST1 Intraosseous (IO) process, and 74.1 mL/minute for IV method[4] and meters the volume of blood delivered to a maximum of 450 mL, which is the optimal amount of blood the donor soldier can provide and still maintain battle readiness.

The blood transfusion meter consists of a removable peristaltic pump head, the meter enclosure and a handle/ball grip assembly. The pump is manually operated by turning the detachable handle and ball grip. The ball grip is large enough to grasp comfortably even while wearing gloves. The meter enclosure

electronically monitors and displays the volume of blood pumped through the device and the pump speed. We have designed the peristaltic pump and pump tube to match the volume of blood for safe reinfusion at a specific rotational speed. The hand pump design allows for operation in the field with no motor or heavy battery that requires charging. A standard low cost, long-lasting thin film battery (CR2032) powers the electronic display and microprocessor.

As blood is pumped through the device, the meter displays the volume of blood transfused. The display also indicates the crank speed, prompting the operator to turn the crank at the correct speed. Steady turning of the handle at the correct rate safely regulates the flow of blood, to protect the donor and patient.

Because the blood is being pumped and metered through the device, users do not need to depend on gravity for reinfusion. This means transfusions can occur in sub-optimal conditions where you don't have the luxury of hanging a bag.

If multiple units of blood are required, the pump head can be removed from the metering enclosure and a new pump head, already connected to the next donor, primed with blood, is snapped on the enclosure for rapid switching from one donor to the next.

We believe this transfusion metering device will be successful because soldiers can operate it in forward areas under harsh environments enabling fast and accurate Human to Human blood transfusions. This device will save lives.

4. Who cares? What difference will this device make?

The military should care. Doctor's care. If the military approves this metering device as standard procedure for emergency care, it will save lives. Trained personnel can conduct transfusions, providing aid faster, with fewer complications than the present method. This metering device might also reduce the amount of wasted blood components, saving a precious resource.

The device is small, inexpensive, and easily included in med kits already carried by troops.

5. What are the risks?

Current US military clinical practice guidelines permit emergency transfusions of non-Food and Drug Administration (FDA)-compliant freshly collected blood products in theaters of war.[5]

There are risks associated with the use of FWB, including but not limited to increased risk of transfusion-transmitted infections (e.g., HIV, hepatitis B/C, syphilis), and an increased risk of clerical errors leading to major mismatch when ABO-identical WB is provided, due to the potentially chaotic and urgent conditions during which FWB is used. Additionally, field conditions are inherently unsanitary and might increase the risk of bacterial contamination of the FWB. Recent history with approximately 10,000 FWB transfusions to U.S. personnel during OIF/OEF have resulted in one Hepatitis C (HCV), one Human T-Lymphocyte Virus (HTLV) seroconversion, and one fatal case of transfusion-associated graft-versus host disease that was potentially due to a FWB transfusion.[6]

FWB SAFETY: *All military personnel, and thus the population of potential walking FWB donors, are screened for or immunized against human immunodeficiency virus (HIV), hepatitis B and C, and other common bloodborne pathogens. Bacterial contamination of FWB is a risk under field conditions but is rare after 8 hours of warm storage in the United States. At the time of collection, all donors undergo standard risk questionnaire screening and are tested for anemia. After each FWB transfusion in theater, samples of both donor and recipient blood are sent to the Armed Forces Blood Program for analysis. The results of this testing have been extensively monitored for rates of infection.33 Of 2,222 donor samples tested between May 2003 and August 2005, there were three hepatitis C antibody confirmations by recombinant immunoblot assay, one sample indeterminate for HIV, and a single human T-cell lymphocytic virus by Western blot. For blood component therapy in the United States, the risk of infection with either HIV or hepatitis C is one for every two million units. Given that FWB transfusion is currently used as a lifesaving therapy in the face of otherwise untreatable coagulopathy, in the absence of the availability of appropriate blood component therapy, the use of fresh whole blood appears to be safe and beneficial.*[3]

6. How much will this new device cost?

To be determined

7. How long will the product development take?

We have developed a fully functioning prototype device. This prototype provides proof of concept.

We will make modifications to the design based on testing and feedback. Final product development, including making tooling for plastic parts will take four to six months.

The military needs to approve Human to Human transfusions as an allowed emergency procedure. We hope the development of our blood metering device will act as a catalyst for gaining approval.

8. What are the mid-term and final "exams" to check for success?

- Testing the prototype to ensure usability and efficacy
- Evaluating feedback and making changes to optimize functionality
- Receiving acceptance and approval from the military
- Investing in the tooling and preparation for mass production

9. Management and Capabilities

Blaster Tech Engineering, headed by Mike McCoy, developed the device. Mike has thirty years' experience in product development and project management. He founded ADS Tech, Inc. in 1992. ADS

developed computer peripherals that were sold to mail order, e-commerce, and retail stores in over 40 countries.

The team at ADS developed many first in the world products such as the first USB MPEG-2 hardware encoder that converted analog video to DVD video. The first OHCI IEEE 1394 FireWire card and the first AM/FM radio receiver card for Windows PC's. ADS received a patent for its RDS radio data encoder technology included in their AM radio receivers. ADS Tech developed more than fifty products and brought them to market.

Scott Coleman is the hardware engineer. He developed the electronics for this device. Scott was the lead hardware engineer for ADS Tech. Scott is also the lead engineer for Medwand (www.medwand.com), a diagnostic medical device. Scott has over thirty years' experience developing hardware, firmware, and software in the medical, consumer, broadcast, and military markets.

Wayne Morris, owner of Ghost Dance Company and his team created the industrial design of the device. Wayne has over 40 years' experience designing and developing products for many industries.

10. Support from Military Doctors

The idea for this device came from a Dr. John Wagner, a military physician in the US Navy, who is frustrated with the current method of emergency transfusions. Dr. Wagner feels that human-to-human blood transfusions make practical sense and believes a blood metering device will save lives.

With the current method a donor fills a collection bag. You know when to stop taking blood from the donor when the bag fills (approximately 450~500 mL). In human-to-human blood transfusions there is no collection bag, so the blood meter solves the problem of taking too much or too little blood from the donor. The device collects the precise amount of blood volume from the donor while delivering fresh whole blood to the patient at the correct reinfusion rate (matching gravity flow) depending on the type of sternal intraosseous access used.

Inquiries and Questions

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References

(1) An approach to transfusion and hemorrhage in trauma: current perspectives on restrictive transfusion strategies. Homer Tien, MD,[*†] Bartolomeu Nascimento, Jr., MD,[†] Jeannie Callum, MD,[†] and Sandro Rizoli, MD, PhD[†] An approach to transfusion and hemorrhage in trauma: current perspectives on restrictive transfusion strategies (nih.gov)

(2) JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG) - Whole Blood Transfusion (CPG ID: 21)

Whole_Blood_Transfusion_15_May_2018_ID21.pdf (army.mil)

6 Spinella PC, Cap AP. Whole blood: back to the future. Curr Opin Hematol. 2016 Nov;23(6):536-542

9 Pidcoke HF, Aden JK, Mora AG, et al. Ten-year analysis of transfusion in Operation Iraqi Freedom and Operation Enduring Freedom: increased plasma and platelet use correlates with improved survival. J Trauma Acute Care Surg. 2012 Dec;73(6 Suppl 5):S445-52.

10 Holcomb JB, Tilley BC, Baraniuk S, et al. Transfusion of plasma, platelets, and red blood cells in a 1:1:1 vs a 1:1:2 ratio and mortality in patients with severe trauma: the PROPPR randomized clinical trial. PROPPR Study Group. JAMA. 2015 Feb 3;313(5):471-82.

11 Spinella PC, Perkins JG, Grathwohl JG, et al. Warm fresh whole blood is independently associated with improved survival for patients with combat-related traumatic injuries. J Trauma. 2009;66:S69-S76.

(3) Fresh Whole blood Transfusion: A Controversial Military Practice ADA480272.pdf (dtic.mil)

(4) Massive Blood Transfusion - Lessons from the Military - **Source:** American Association of Nurse Anesthetists Massive Blood Transfusion - Lessons from the Military - HealthManagement.org

(5) Emergency sternal intraosseous access for warm fresh whole blood transfusion in damage control resuscitation - PubMed (nih.gov) Christopher Kalhagen Bjerkvig[1], Theodor Kaurin Fosse, Torunn Oveland Apelseth, Joar Sivertsen, Hanne Braathen, Håkon Skogrand Eliassen, Anne Berit Guttormsen, Andrew P Cap, Geir Strandenes

(6) Transfusion-transmissible viral infections among US military recipients of whole blood and platelets during Operation Enduring Freedom and Operation Iraqi Freedom - PubMed (nih.gov)

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