

Editorial Review

The Time to Field Freeze Dried Plasma is Now

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Plasma is the component of blood that remains once all cells and platelets are removed and contains the factors required for effective coagulation during hemorrhage. It is a critical component of damage control resuscitation of seriously injured combat casualties. Plasma administration replaces depleted clotting factors and restores intravascular volume without the risk of creating a dilutional coagulopathy. In the setting of trauma care, plasma is a much better resuscitative fluid than the crystalloids (e.g., normal saline) and colloids (e.g., hetastarch) currently deployed with U.S. forces for battlefield use. In the United States, plasma is typically stored in a fresh frozen form that must be carefully thawed and warmed prior to administration. Fresh frozen plasma (FFP) has to be administered within 24 hours of thawing, which means that pre-mission preparation for potential casualties could rapidly deplete theater stocks.

Since the carrying and thawing of frozen liquids is impractical on the battlefield and in other austere environments, Germany developed and licensed a freeze-dried version of plasma (LyoPlas N-w), which consists of a powder that can be rapidly reconstituted with water prior to intravenous administration, but is not approved by the U.S. Food and Drug Administration (FDA). A similar research and development effort is underway in the U.S. to produce an FDA approved, freeze dried plasma (FDP), but is not expected to result in fielding until the 2015 to 2017 timeframe. Significant legal barriers exist that prevent U.S. military medical personnel from using non-FDA approved medications and blood products on U.S. servicemembers. Even though seriously wounded American casualties are being successfully treated with LyoPlas N-w by German medical facilities in Afghanistan, U.S. Special Operations Forces (SOF) medics are prohibited from using this same product on the battlefield hours earlier as a potentially lifesaving measure. Recognizing the illogic of this disparity and the great potential FDP holds for trauma resuscitation, the Office of the U.S. Special Operations Command (USSOCOM) Command Surgeon is actively pursuing authorization for SOF to field LyoPlas N-w.

LyoPlas N-w is produced in Germany following the European Union Good Manufacturing Practices guidelines. Each unit of LyoPlas N-w comes from a single donor, who is screened for all required blood-borne pathogens, including HIV, Hepatitis A, B, and C, as well as Parvovirus B19. After lyophilization the unit is placed into a minimum four-month quarantine until the donor can be retested for these pathogens to ensure continued health and that no delayed seroconversion has occurred. These measures to reduce the risk of infectious disease transmission to the recipient meet or exceed U.S. blood banking standard practices. Unlike FFP, LyoPlas N-w additionally undergoes filtration to further remove cellular remnants and reduce the risk of infection or transfusion immune reactions. It remains efficient for at least 12 months when maintained in a temperature range of 4 to 25 degrees Celsius. Germany has to date fielded over 500,000 units of LyoPlas N-w without any unusual or significant adverse effects when compared to FFP. Multiple clinical studies have also demonstrated that LyoPlas N-w is at least as efficacious as FFP.

SOF requires a more effective combat casualty resuscitation fluid than colloids and crystalloids. While warm fresh whole blood is a viable option, buddy transfusions are not always feasible based on the operational environment. FDP has the potential to effectively fill a critical gap in the tools available to the SOF medic. The U.S. efforts to produce an FDA approved, lyophilized plasma will not come to fruition for at least five more years. Since a coalition partner already produces an apparently effective and safe FDP and uses it on U.S. combat casualties, senior DoD medical leaders should act quickly to approve the USSOCOM request to field it as well.

REFERENCE: This editorial is based on information obtained from the German FDA-equivalent package insert and a review article in the German *Journal of Transfusion Medicine*, as well as personal communications with the German military/Red Cross.

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