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ARMED FORCES SEARCH FOR WAYS TO IMPROVE SURVIVAL IN THE COMBAT ZONE

New recommendations can help medical arms of the military meet their mission

(July 25, 2005) Bethesda, MD – As reported last December in the *New England Journal of Medicine*, the U.S. military's on-the-ground surgical strategy now aims at "damage control, not definitive repair, unless it can be done quickly." Today's mobile medical teams, equipped with powerful and efficient tools, provide care near the battlefront to treat extensive injuries resulting from mortar attacks and suicide bombers. Despite new strategies and improved care, hemorrhage (blood loss) – caused by bullets and exploding munitions fragments – continues to kill in combat.

Military experts believe that blood loss may be one of the most preventable causes of battlefield fatalities. With thousands of lives at risk and millions of dollars at stake for product development, two branches of the military are collaborating to find new resuscitative products that can be easily transported and used on the frontline. These products must be effective in reducing blood-loss-related fatalities. A new report outlines how the military can best identify, nurture and support the next generation of resuscitation fluids and adjunct therapies.

The Study

The new report, entitled *Recommendations for Reviewing Research on Advanced First-Responder Resuscitation Fluids and Adjunct Therapies,* was prepared at the request of the U.S. Army Medical Research and Materiel Command and the Office of Naval Research by the Life Sciences Research Office, Inc. (LSRO) (<u>www.LSRO.org</u>). LSRO is a non-profit research and analysis firm that distinguishes itself by its third-party independence and the use of seasoned staff researchers and outside experts to investigate important topic areas.

In the first phase of the study, LSRO's expert panel reviewed and ranked 59 research preproposals for resuscitation fluids and adjunct therapies in an effort to determine which held the most promise for improving survival from combat blood-loss and achieving sound scientific advances. This phase was designed to assist the military in determining which emerging products were worthy of further review and potential future funding. Of the 59 pre-proposals, 49 were in the pre-clinical stage of development, in which a product's effects and toxicity are evaluated using animal models and cell cultures. Ten of the pre-proposals were in the clinical stage of development, which is a follow-on phase that establishes the product's safety and effectiveness in humans. The types of novel resuscitation fluids and adjunct therapies considered by the panelists included blood volume expanders and drugs that enhanced oxygen delivery, protected cells, improved cardiovascular responses, minimized inflammation and/or modulated the immune system.

In the second phase of the study, the expert panel examined the forms and processes by which the military obtains and reviews information related to scientific research. This phase was designed to identify opportunities for improvements in gathering better, more meaningful data with which to evaluate future proposals.

Findings

The expert panel identified several products in various stages of development that were durable enough for combat use and had preliminary data suggesting they possess the potential to improve the treatment of life-threatening hemorrhage.

Recommendations

The panel made the following recommendations:

- Product investigations should be divided into two categories: one for blood volume expanders and another for pharmacologic agents that can be used with or without resuscitation fluids;
- Given that civilian treatment of individuals who have been involved in car accidents is the best surrogate model for treating combat-inflicted hemorrhage, data from experimental resuscitation products used by emergency medical technicians should be included as a part of all study data;
- Pre-clinical studies should be funded for a maximum of two years and clinical studies should be funded for a maximum of three years, with future funding potential based on achieving key milestones and objectives; and
- Standardized formats and requirements should be adopted for research proposals. The expert panel had created proposal instructions and forms as part of its work product.

Conclusions

The mission of the military medical services is to ensure that deployed medical units are trained, equipped, and capable of supporting the medical requirements of deployed forces under any contingency. The findings and recommendations of this study enable the medical arms of the military to further advance their capabilities in treating life-threatening hemorrhage and effectively meet their mission.

The military will invite investigators of pre-proposals having the greatest military relevance and scientific merit to submit full proposals for possible funding. The next challenge for the military is to select those candidates that hold the most promise for a durable, safe, and effective product that can be used by medics and combat lifesavers on the frontline and foster product development.

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For nearly half a century, the Life Sciences Research Office (LSRO) has provided expert objective sciencebased analysis and advice to governmental agencies and leading corporations in the food, health and bioscience sectors. LSRO is a non-profit organization that was originally established by the Federation of American Societies for Experimental Biology.

Editor's Note: A copy of the full report is available to the press. An executive summary is available to the public online at <u>www.LSRO.org</u>. To schedule an interview with an LSRO researcher, please contact Donna Krupa at 703.527.7357 (office), 703.967.2751 (cell) or <u>djkrupa1@aol.com</u>.