Office Of The Secretary Of Defense (OSD)
Deputy Director Of Defense Research & Engineering
Deputy Under Secretary Of Defense (Science & Technology)
Small Business Innovation Research (SBIR)
FY2005.2 Program Description

Introduction

The Deputy Under Secretary of Defense (Science & Technology) SBIR Program is co-sponsoring topics with Defense Health Affairs. In order to participate in the OSD SBIR Program this year, all potential proposers should register on the DoD SBIR website as soon as you can, and should follow the instruction for electronic submittal of proposals. It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at http://www.dodsbir.net/submission. If you experience problems submitting your proposal, call the help desk (toll free) at 1-866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The DoD SBIR Proposal Submission Website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report.

We WILL NOT accept any proposals that are not submitted through the on-line submission site. The submission site does not limit the overall file size for each electronic proposal, there is only a page limit. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. If you wish to upload a very large file, it is highly recommended that you submit prior to the deadline submittal date, as the last day is heavily trafficked. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

Firms with strong research and development capabilities in science or engineering in any of the topic areas described in this section and with the ability to commercialize the results are encouraged to participate. Subject to availability of funds, the DUSD(S&T) SBIR Program will support high quality research and development proposals of innovative concepts to solve the listed defense-related scientific or engineering problems, especially those concepts that also have high potential for commercialization in the private sector. Objectives of the DUSD(S&T) SBIR Program include stimulating technological innovation, strengthening the role of small business in meeting DoD research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technological innovation, and increasing the commercial application of DoD-supported research and development results. The guidelines presented in the solicitation incorporate and exploit the flexibility of the SBA Policy Directive to encourage proposals based on scientific and technical approaches most likely to yield results important to DoD and the private sector.

Description of the OSD SBIR Three Phase Program

Phase I is to determine, insofar as possible, the scientific or technical merit and feasibility of ideas submitted under the SBIR Program and will typically be one half-person year effort over a period not to exceed six months, with a dollar value up to $100,000. We plan to fund 3 Phase I contracts, on average, and downselect to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund this many. Proposals should concentrate on that research and development which will significantly contribute to proving the scientific and technical feasibility of the proposed effort, the successful completion of which is a prerequisite for further DoD support in Phase II. The measure of Phase I success includes technical performance toward the topic objectives and evaluations of the extent to which Phase II results would have the potential to yield a product or process of continuing importance to DoD and the private sector, in accordance with Section 4.3.

Subsequent Phase II awards will be made to firms on the basis of results from the Phase I effort and the scientific and technical merit of the Phase II proposal in addressing the goals and objectives described in the topic.

Phase II awards will typically cover 2 to 5 person-years of effort over a period generally not to exceed 24 months (subject to negotiation). Phase II is the principal research and development effort and is expected to produce a well defined deliverable prototype or process. A more comprehensive proposal will be required for Phase II.

Under Phase III, the DoD may award non-SBIR funded follow-on contracts for products or processes, which meet the component mission needs. This solicitation is designed, in part, to encourage the conversion of federally sponsored research and development innovation into private sector applications. The small business is expected to use non-federal capital to pursue private sector applications of the research and development.

This solicitation is for Phase I proposals only. Any proposal submitted under prior SBIR solicitations will not be considered under this solicitation; however, offerors who were not awarded a contract in response to a particular topic under prior SBIR solicitations are free to update or modify and submit the same or modified proposal if it is responsive to any of the topics listed in this section.

For Phase II, no separate solicitation will be issued and no unsolicited proposals will be accepted. Only those firms that were awarded Phase I contracts, and have successfully completed their Phase I efforts, will be invited to submit a Phase II proposal. Invitations to submit Phase II proposals will be released at or before the end of the Phase I period of performance. The decision to invite a Phase II proposal will be made based upon the success of the Phase I contract to meet the technical goals of the topic, as well as the overall merit based upon the criteria in section 4.3. DoD is not obligated to make any awards under Phase I, II, or III. DoD is not responsible for any money expended by the proposer before award of any contract. For specifics regarding the evaluation and award of Phase I or II contracts, please read the front section of this solicitation very carefully. Every Phase II proposal will be reviewed for overall merit based upon the criteria in section 4.3 of this solicitation, repeated below:

a. The soundness, technical merit, and innovation of the proposed approach and its incremental progress toward topic or subtopic solution.
b. The qualifications of the proposed principal/key investigators, supporting staff, and consultants. Qualifications include not only the ability to perform the research and development but also the ability to commercialize the results.
c. The potential for commercial (defense and private sector) application and the benefits expected to accrue from this commercialization.

In addition, the OSD SBIR Program has a *Phase II Plus* Program, which provides matching SBIR funds to expand an existing Phase II that attracts investment funds from a DoD acquisition program or Private sector investments. ***Phase II Plus*** allows for an existing Phase II OSD SBIR effort to be extended for up to one year to perform additional research and development. ***Phase II Plus*** matching funds will be provided on a one-for-one basis up to a maximum $250,000 of SBIR funds. All ***Phase II Plus*** awards are subject to acceptance, review, and selection of candidate projects, are subject to availability of funding, and successful negotiation and award of a ***Phase II Plus*** contract modification.

The Fast Track provisions in section 4.0 of this solicitation apply as follows. Under the Fast Track policy, SBIR projects that attract matching cash from an outside investor for their Phase II effort have an opportunity to receive interim funding between Phases I and II, to be evaluated for Phase II under an expedited process, and to be selected for Phase II award provided they meet or exceed the technical thresholds and have met their Phase I technical goals, as discussed Section 4.5. Under the Fast Track Program, a company submits a Fast Track application, including statement of work and cost estimate, within 120 to 180 days of the award of a Phase I contract (see the Fast Track Application Form on www.dodsbir.net/submission). Also submitted at this time is a commitment of third party funding for Phase II. Subsequently, the company must submit its Phase I Final Report and its Phase II proposal no later than 210 days after the effective date of Phase I, and must certify, within 45 days of being selected for Phase II award, that all matching funds have been transferred to the company. For projects that qualify for the Fast Track (as discussed in Section 4.5), DoD will evaluate the Phase II proposals in an expedited manner in accordance with the above criteria, and may select these proposals for Phase II award provided: (1) they meet or exceed selection criteria (a) and (b) above and (2) the project has substantially met its Phase I technical goals (and assuming budgetary and other programmatic factors are met, as discussed in Section 4.1). Fast Track proposals, having attracted matching cash from an outside investor, presumptively meet criterion (c). However,

selection and award of a Fast Track proposal is not mandated and DoD retains the discretion not to select or fund any Fast Track proposal.

Follow-On Funding

In addition to supporting scientific and engineering research and development, another important goal of the program is conversion of DoD-supported research and development into commercial (both Defense and Private Sector) products. Proposers are encouraged to obtain a contingent commitment for follow-on funding prior to Phase II where it is felt that the research and development has commercialization potential in either a Defense system or the private sector. Proposers who feel that their research and development have the potential to meet Defense system objectives or private sector market needs are encouraged to obtain either non-SBIR DoD follow-on funding or non-federal follow-on funding, for Phase III to pursue commercialization development. The commitment should be obtained during the course of Phase I performance, or early in the Phase II performance. This commitment may be contingent upon the DoD supported development meeting some specific technical objectives in Phase II which if met, would justify funding to pursue further development for commercial (either Defense related or private sector) purposes in Phase III. The recipient will be permitted to obtain commercial rights to any invention made in either Phase I or Phase II, subject to the patent policies stated elsewhere in this solicitation.

Contact with DoD

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the topic authors and point of contact identified in the topic description section. Proposals should be electronically submitted. Oral communications with DoD personnel regarding the technical content of this solicitation during the pre-solicitation phase are allowed, however, proposal evaluation is conducted only on the written submittal. Oral communications during the pre-solicitation period should be considered informal, and will not be factored into the selection for award of contracts. Oral communications subsequent to the pre-solicitation period, during the Phase I proposal preparation periods are prohibited for reasons of competitive fairness. Refer to the front section of the solicitation for the exact dates.

Proposal Submission

Proposals shall be submitted in response to a specific topic identified in the following topic description sections. The topics listed are the only topics for which proposals will be accepted. Scientific and technical information assistance may be requested by using the SBIR/STTR Interactive Technical Information System (SITIS).

It is required that all bidders submit their proposal cover sheet, company commercialization report and their firm's technical and cost proposal form electronically through the DoD SBIR/STTR Proposal Submission Website at http://www.dodsbir.net/submission. If you experience problems submitting your proposal, call the help desk (toll free) at 866-724-7457. You must include a Company Commercialization Report as part of each proposal you submit; however, it does not count against the proposal page limit. Please note that improper handling of this form may result in the proposal being substantially delayed. Information provided may have a direct impact on the review of the proposal. The proposal submission website allows your company to come in any time (prior to the proposal submission deadline) to edit your Cover Sheets, Technical and Cost Proposal and Company Commercialization Report. We **WILL NOT accept any proposals which are not submitted through the on-line submission site.** The submission site does not limit the overall file size for each electronic proposal, only the number of pages is limited. However, file uploads may take a great deal of time depending on your file size and your internet server connection speed. You are responsible for performing a virus check on each technical proposal file to be uploaded electronically. The detection of a virus on any submission may be cause for the rejection of the proposal. We will not accept e-mail submissions.

The following pages contain a summary of the technology area, which is followed by the topics.

DUSD(S&T)/Defense Health Program
Biomedical Technology

The Department of Defense is aggressively pursuing unified Force Health Protection and Treatment strategies to protect and treat Service members and their family members from health hazards associated with military service. Toward that end, DoD is undertaking strategies that save lives and promote healthy units and communities while improving both force morale and war fighting capabilities.

The operational force is exposed to health threats throughout the operational continuum, from CONUS fixed facilities (garrison, base, ashore) through deployment, employment, and redeployment. DoD is developing policy and procedures to assess occupational and environmental health threats for all locations. A comprehensive record of current health—and of past health events and resultant exposure levels—will be maintained for as many as 100,000 U.S. military personnel over their entire military-service cycle (the Millennium Cohort Study).

When Force Health Protection capabilities are fully implemented, commanders will have a more complete view of potential health threats. Integration of assessments from health databases and other assessments from intelligence (e.g., about land mines, directed enemy fire, fratricide) and safety (e.g., about injuries, vehicle accidents, explosives, aviation mishaps) will provide a framework for identifying future medical technology capabilities necessary for Force Health Protection.

In addition to occupational and environmental hazards, the weaponry of our allies and enemies continues to improve. The treatment of battlefield casualties is exacerbated by the long evacuation times often found in military operations. This requires battlefield medics and physicians assistants to stabilize patients for extended periods and makes battlefield trauma care markedly different from civilian trauma care. Because approximately 86% of all battlefield deaths occur within the first 30 minutes after wounding, the abilities to rapidly locate, diagnose, and render appropriate initial treatments are vital to reversing the historical outcomes of battlefield injuries. The need to provide such care with a reduced logistics footprint is the cornerstone around which the future of combat casualty care research is built.

Ensuring the health of the force encompasses several key capabilities:

- To provide FDA-approved prevention, diagnosis and treatment items for disease and injury;
- To mobilize, deploy and sustain field medical services and support for any operation requiring military services;
- To maintain and project the continuum of healthcare resources required to provide for the health of the force;
- To operate in conjunction with beneficiary healthcare; and
- To develop training systems which provide realistic rehearsal of emergency medical and surgical procedures and unit-level medical operations.

These capabilities comprise an integrated and focused approach to protect and sustain DoD's most important resource—its Service members and their families—throughout the entire length of service commitment.

Three broad capability areas of particular interest are tools and techniques for risk communication, for epidemiology research, and for delivery of health education and training unique to DoD functions. These are described in more detail below:

Health Risk Assessment and Communication Decision Tools: Risk analysis is a science-based process that strives to reflect the realities of nature as accurately as possible. The Department experienced significant challenges in determining and communicating risk on illnesses among Gulf War veterans, such as that for the anthrax vaccination program, as well as other deployments. A decision support tool is needed that produces a likelihood index of risk based on epidemiological, intelligence, environmental exposure, and health information concerning deployed forces. Further, risk communication strategies commensurate with the determined risk likelihood should be incorporated into the support tool. The tool should also allow for predictive modeling of the rate of reporting of real and somatic symptoms given a communication strategy.

New Methods to Monitor Health Status: Monitoring of health status during deployments is necessary to determine etiologic factors of deployment related health change. Data and information analysis tools are needed to collect and harmonize disparate data and information sources and to provide health status surveillance pre- or post-

injury to medical information consumers within and outside of military medical channels. Health monitoring should be for a sharply limited set of physiologically based indicators, and should yield an unambiguous interpretation of health status. Projects are required to have a strong biological basis and be sensitive to changes in health status based on real-time measurements from warfighters in an operational environment.

Force Health Training and Learning Tools: Developing and maintaining diagnostic and treatment skills among military physicians—as well as lifesaving buddy- and self-aid skills among other military personnel and laymen—are important aspects of deployment health. Advanced distributed learning, simulation-based training and other computer-based training technology should enable all health-care personnel to assist in emergency situations involving traumatic injury and other acute health crises, and should assist medical professionals to maintain clinical knowledge and skills. Tools that can be extended to use by patients and the general military population for proactive preventive medicine are desirable. Tools should be based on existing medical and pharmacological knowledge, should be universally accessible, should allow for unlimited practice, and should be SCORM-compliant in content and in delivery modalities.

Combat Casualty Care Interventions: Minimizing Blood Loss and Optimizing Fluid Resuscitation. The principal cause of death among soldiers who are killed outright by an injury is hypovolemia secondary to hemorrhage. Enhanced means are sought to limit actual and functional volume losses and to limit the immediate, short- and long-term consequences of such hemorrhages. Products are needed to enhance capabilities for control of hemorrhage, stabilization and resuscitation from hemorrhage, and development of noninvasive sensors to determine tissue viability and perfusion. This research area includes drugs or implantable devices for enhanced healing of soft tissue and bone defects caused by military ballistic injury, development of non-invasive sensors to determine tissue viability and perfusion, identifying and testing techniques, drugs and treatments to enhance vascular repair, identifying improved plasma substitutes for resuscitation of burn victims, identifying improved techniques and assessing commercial materiel developments applicable to surgical management of primary ballistics and thermal burn injuries, and identifying improved techniques for management of primary blast, crush and chemical burn injuries. Examples of specific products or efforts which might be addressed include materiel for the pharmacological or surgical management of high-velocity ballistics and fragment wounds, and blast injuries. Materiel of interest include agents that promote neuronal regeneration, bone repair/regeneration, vascular healing and regeneration, development of plasma substitutes for burn and shock, treatment of chemical burns, equipment and procedures for emergency airway management and mechanical ventilation of severely injured casualties.

The DUSD(S&T)/DHP biomedical topics are:

OSD05-H01	Miniature Disposable Drug Infusion Pumps with Improved Safety Features and Embedded Computer Control (Army MRMC)
OSD05-H02	Reducing the Areal Density and Enhancing Performance of Ballistic Resistant Polymers (Army MRMC)
OSD05-H03	Development of an Intracavitary Hemostatic Agent for Use in Noncompressible Hemorrhage (Army MRMC)
OSD05-H04	Use of Non-Invasive Methods to Determine Stroke Volume (Army MRMC)
OSD05-H05	Development of Novel Methods and Reagents for Prion Infection (Army MRMC)
OSD05-H06	The Use of Proteomics for Surrogate Markers of Prion Infection (Army MRMC)
OSD05-H07	Development of a Multiplexed Point-of-Care Assay for the Detection of Infectious Agents Causing Fever in Deployed Soldiers (Army MRMC)
OSD05-H08	Tool for Pharmacovigilance: for Infectious Disease, Combat Casualty Care and Biological Warfare and Chemical Defense Medications and Vaccines (Army MRMC)
OSD05-H09	Regional Anesthesia Simulator for Training of Resident and Staff Pain Management Specialists (Army MRMC)
OSD05-H10	Mechanisms for Hands-Free Point of Care Data Entry in Combat Environments (Army MRMC)
OSD05-H11	Wearable Biomechanical and Physiological Monitoring Apparatus for Amputees (Army MRMC)
OSD05-H12	Portable Pulmonary Injury Diagnostic Device (Navy ONR)
OSD05-H13	Vertical Linear Accelerator for Dynamic Visual-Vestibular Acuity Health Status Evaluation and Desensitization Training (Navy NAMRL)
OSD05-H14	MedNet: An Agent Based Medical Treatment Support Tool (Navy ONR)
OSD05-H15	Smart Hemodynamic Monitoring System for Critical Care Air Transport Team (CCATT) (Air Force AFRL)

OSD SBIR 05.2 Topic Index

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OSD05-H14	MedNet: An Agent Based Medical Treatment Support Tool
OSD05-H15	Smart Hemodynamic Monitoring System for Critical Care Air Transport Team (CCATT)

OSD05-H01 TITLE: Miniature Disposable Drug Infusion Pumps with Improved Safety Features and Embedded Computer Control

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Investigate new fluid pumping mechanisms and implement new design strategies with the goal of building a miniature, disposable, self-contained infusion pump for safe and precise delivery of pharmacologic agents and drugs capable of programmable control.

DESCRIPTION: Infusion pumps for intravenous drug infusion are large, heavy and difficult to use in en route care environments. For military applications, a significant advantage in weight and cube savings and equipment maintenance could be obtained if drug infusion pumps could be made very small (size of a quarter), precise in their flow rate control, disposable and resistant to bubble formation at altitude and in high vibration environments, such as those encountered in air and ground evacuation vehicles. In addition, safe delivery of drugs and pharmacologic agents depends on risk mitigation approaches to minimize the potential of dosage calculation errors, delivery rate errors, and improper matching of drug to dosage. A significant increase in patient safety could be achieved by designing an infusion pump system that minimizes these potential errors and could be made small and cheaply enough to be made disposable. For example, linking a drug identification system with limits on the drug delivery parameters of the pump could help to reduce the errors in drug delivery. In addition, drug delivery pumps currently work on metering mechanisms without direct monitoring of the delivered flow. Development of a miniature flow measurement capability would significantly improve the safety of drug infusion pumps. Recent advances in micro-machining technologies, development in microfluidic systems and the miniaturization of embedded processors make it feasible to design an infusion pump capable of being encoded to follow fixed or even dynamic changes in the fluid infusion rate that might be dictated by changes in a particular physiological end-point or by a pre-programmed pharmaco-dynamic model. For example, a chronotropic agent might be titrated to achieve a target heart rate or an intravenous anesthetic agent might be delivered in accordance with a pharmacokinetic and dynamic model of the drug.

PHASE I: Collect requirements and conduct an analysis of design alternatives of candidate fluid delivery mechanisms that would be suited to the manufacturing requirements of a miniature, quarter-sized, battery-operated, disposable infusion pump that will cover the full range of commonly used pharmacologic agents and operate for 24 hrs. Develop an accurate and reliable method of flow monitoring to affirm delivery rates and design a strategy for improved safety features.

PHASE II: Build and characterize the pump characteristics in terms of flow rate precision, stability of delivery, susceptibility to bubble formation, sensitivity to upstream and downstream occlusion and power requirements. Test and evaluate programmable functionality and safety features of the design aimed at minimizing errors of dosage and drug identification. Evaluate controlled drug delivery in animal models using target-controlled anesthesia (TCA), for example.

PHASE III: Conduct clinical evaluations of drug delivery and assess the safety benefit of the improved design aimed at minimizing dosing errors.

REFERENCES:
1. "To Err is Human: Building a Safer Health System." Institute of Medicine Health Care Quality Initiative, LT Kohn, JM Corrigan and MS Donaldson, Eds. November, 1999.

KEYWORDS: drug infusion pump, microprocessor control, safety, programmable, drugs, pharmacologic agents, disposable, miniature

OSD05-H02 TITLE: Reducing the Areal Density and Enhancing Performance of Ballistic Resistant Polymers

TECHNOLOGY AREAS: Materials/Processes, Biomedical, Human Systems

ACQUISITION PROGRAM: DSA, MRMC

OBJECTIVE: To add a hard transparent strike face to a ballistic resistant polymer, that will enhance ballistic protection while reducing areal density. The strike face should also prevent the polymer from becoming scratched and increase its resistance to chemical degradation.

DESCRIPTION: Addition of a transparent ceramic strike face to ballistic resistant materials is usually done for two reasons: (1) to reduce the areal density of the shield, while maintaining or enhancing performance compared with an all-polymer ballistic resistant shield; and (2) it prevents scratching and chemical degradation of the ballistic resistant polymer. Many ceramic materials have been used to produce ballistic armor products; however, these materials in personal protective armor are limited by their high density and in many cases extremely high cost of manufacture. On the other hand, innovative usage of other transparent materials for a hard strike face may be as good as or better than most oxide and non-oxide ceramics.

PHASE I: Determine the feasibility for forming innovative transparent materials that can be bonded to ballistic resistant polymers that (1) prevents scratching and chemical degradation of the ballistic resistant polymer; and (2) as the composite (i.e., innovative transparent material and ballistic resistant polymer) has an areal density less than 3.0 lb/ft(2) and provides NIJ Armor Type IIIA protection.

PHASE II: Form curvilinear transparent strike face material and bond it to ballistic resistant polymers that (1) reduces areal density while maintaining performance compared with an all-polymer ballistic resistant material; and (2) prevents scratching and chemical degradation of the ballistic resistant polymer. Develop and test a prototype under actual use conditions that provides NIJ Armor Type IIIA protection.

PHASE III DUAL-USE APPLICATIONS: U.S. military forces do not wear face and eye protection because devices providing NIJ Armor Type IIIA protection effectively doubles the weight a soldier carries on his head compared with the PASGT (personnel armor system, ground troops) Kevlar helmet alone. Many civilian law-enforcement officers are inadequately protected from ballistic injuries to the face and neck because commercial-off-the-shelf shields are too heavy and unwieldy or they are too expensive. Low-cost methods for forming protective materials would have many applications and benefits for law-enforcement, military, and the aviation and security glazing industries.

OPERATING AND SUPPORT COST (OCSR) REDUCTION: During Operation Desert Storm, nearly twenty-two percent of soldiers treated at U.S. Army Seventh Corps Hospitals for ballistic injuries had wounds to the head and neck, and 13 % of ground war casualties were treated for ophthalmic injuries. Although ballistic wounds to the face, head and neck account for a small percentage of battle injuries, they are usually associated with a poor prognosis, moreover, ballistic head wounds received in combat account for almost one-half of immediate deaths attributable to a single wound. Face-shields that resist penetration by high/low velocity and high/low mass missiles will reduce battlefield death and injury rates.

REFERENCES:
1. Sadanandan, S., & Hetherington, J.G. (1997). Characterization of ceramic/steel and ceramic/aluminum armours subjected to oblique impact. International Journal of Impact Engineering, 19, 811-819.

2. Dehmer, P.G., & Klusewitz, M.A. (2002). High performance visors. Aberdeen Proving Ground, MD: Army Research Laboratory. (NTIS No. ADA406301).

3. National Institute of Justice. (1985). Ballistic Resistant Protective Materials (NIJ Standard 0108.01). Rockville, MD: National Criminal Justice Department.

4. Commercial Item Description. (2000). A-A-59537: Face Shield, Ballistic. Philadelphia: Defense Automation and Production Service.

5. Heier, J.S., Enzenauer, R.W., Wintermeyer, S.F., Delaney, M., & LaPiana, F.P. (1993). Ocular injuries and diseases at a combat support hospital in support of Operations Desert Shield and Desert Storm. Archives of Ophthalmology, 111(6). 795-798.

6. Mader, T.H., Aragones, J.V., Chandler, A.C., Hazlehurst, J.A., Heier, J., Kingham, J.D., & Stein, E. (1993). Ocular and ocular adnexal injuries treated by United States military ophthalmologists during Operations Desert Shield and Desert Storm. Ophthalmology, 100(10), 1462-1467.

KEYWORDS: Ballistic, armor, face-shield, eye protection

OSD05-H03 TITLE: Development of an Intracavitary Hemostatic Agent for Use in Noncompressible Hemorrhage

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To develop an intracavitary hemostatic agent for testing in combat-relevant animal models of severe noncompressible hemorrhage. If successful, this hemostatic agent would proceed to clinical trials for treatment of severe intracavitary hemorrhage.

DESCRIPTION: Noncompressible hemorrhage (i.e., hemorrhage not accessible to direct pressure) continues to be a primary cause of death in both military and civilian trauma (1-2). Currently, there is no treatment short of surgery for severe abdominal bleeding resulting from either blunt or penetrating injury. One concept that has been suggested is the development of a hemostatic agent that can be placed directly into the abdominal cavity (through a trocar or similar device) that would promote coagulation and provide internal tamponade (3). Development of an agent that requires direct interaction with the injured tissue to provide hemostasis is problematic because of the difficulty that this agent might have in reaching the injured tissue through pooled or flowing blood. If an agent that requires direct interaction with the injured tissue is proposed, the development of a delivery system that will overcome this obstacle must also be proposed. The current effort is to develop and test a prototype intracavitary hemostatic agent that will be efficacious in militarily-relevant animal models of severe intracavitary hemorrhage. Additionally, use of this agent must be safe (i.e., not produce abdominal compartment syndrome) and must meet requirements for battlefield use (i.e., be low-weight, low-volume, and low-cube; require minimal or no mixing of components; able to be stored/used at environmental temperature) by medical personnel at the training level of combat medics.

PHASE I: Develop a putative hemostatic agent that is likely to promote coagulation and provide hemostasis without manual compression under conditions of severe intracavitary hemorrhage. Successful completion of Phase I will result in development of an agent that could reasonably proceed to animal testing. Preliminary “proof-of-concept” experimentation in ex vivo models (e.g., testing for adhesiveness to ex vivo tissue) is desired for demonstration of efficacy.

PHASE II: Synthesize the putative hemostatic agent and perform preclinical animal testing in animal models of severe trauma. Requirements for successful completion of this phase include successful use in a well-controlled animal study using a standard model of severe venous/parenchymal injury where the agent is introduced into a closed abdomen. Success therefore requires effective delivery to the injured tissue (if this is required for hemostasis) and/or achievement of hemostasis. The study should be performed with sufficient group sizes to demonstrate statistical significance in terms of blood loss and survivability. Successful completion of Phase II will result in a hemostatic agent/device that is ready for entry into clinical studies.

PHASE III: Because of the high incidence of life-threatening hemorrhage associated with both military and civilian trauma, an intracavitary hemostatic agent/device would have wide applicability in trauma centers throughout the world. Such an agent will decrease the significant mortality secondary to uncontrolled hemorrhage and has the potential to decrease adverse sequelae subsequent to hemorrhage.

REFERENCES:
1. Bellamy RF. The causes of death in conventional land warfare: Implications for combat casualty care research. Mil. Med. 1984; 149:55-62.

2. Sauaia A, Moore FA, Moore EE, Moser KS, Brennan R, Read RA, Pons PT. Epidemiology of trauma deaths: A reassessment. J. Trauma 1995; 38:185-193.

3. Holcomb JB, McClain JM, Pusateri AE, Beall D, Macaitis JM, Harris RA, MacPhee MA, Hess JR. Fibrin sealant foam sprayed directly on liver injuries decreases blood loss in resuscitated rats. J. Trauma 2000; 49:246-250.

KEYWORDS: intracavitary hemostasis, noncompressible hemorrhage

OSD05-H04 TITLE: Use of Non-Invasive Methods to Determine Stroke Volume

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: The objective of this topic is to determine whether non-invasive instruments can be used to detect changes in stroke volume that may indicate deterioration in a casualty's condition.

DESCRIPTION: Presently medics treating wounded casualties on the battlefield have no means to anticipate deterioration of a casualty due to undetected bleeding. Medics are able to check heart rate and blood pressure. However, by the time heart rate and blood pressure show problems with a patient, the patient is already in trouble. Medics need a tool to warn them that a patient is headed for trouble. Measuring stroke volume may be a way to anticipate the future condition of a patient. A decrease in volume may indicate undetected internal bleeding and alert the medic to potential problems. The medic needs a small, hand-held, non-invasive instrument to measure stroke volume and alert him/her to potential dangers for the patient.

PHASE I: In Phase I the contractor(s) should demonstrate both in theory and practice that their method actually detects conditions within the heart that will lead to a determination of stroke volume. The size of the instrument is not important for Phase I but the contractor(s) should demonstrate the potential to package the instrument into a hand-held device.

PHASE II: In Phase II the contractor(s) should build a working prototype that is hand-held in size and hardened for combat use. The contractor(s) should test the instrument to ensure that it works correctly and accurately predicts that a decrease in stroke volume directly correlates to a deteriorating patient condition. The contractor(s) should also develop any software algorithms necessary to translate instrument measurements into information that is useful to the medic.

PHASE III DUAL USE APPLICATIONS: The development of an instrument to determine stroke volume has applications for combat medics of all services. In addition, it will be useful for first responders and paramedics in the civilian community to get a non-invasive look at accident victims and determine their potential for problems.

REFERENCES:
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KEYWORDS: stroke volume, micro impulse/ultra-wideband radar, non-invasive instrumentation, combat medic, trauma care

OSD05-H05 TITLE: Development of Novel Methods and Reagents for Prion Infection

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Prion-related diseases e.g. Transmissible spongiform encephalities (TSEs), are inevitably neurodegenerative diseases of long incubation affecting humans and animals. Prions are believed to be abnormal folded proteins (PrPsc) that can replicate by converting normal prion protein (PrPc) into the altered conformation associated with disease (1). Efforts to eradicate prion infections have presented significant challenges because there are currently no rapid diagnostic tests for prion diseases in live animals or humans (2 & 3). To protect military and civilian personnel, there is an urgent need to develop novel reagents and to develop a method of using the reagents that could detect preclinical prion infection in humans and animals. These reagents also could be used as intervention measures to prevent or treat prion disease.

DESCRIPTION: The primary purpose of this topic solicitation is to develop critical early detection methods for prion infection. These efforts to develop a new, sensitive, early detection method should be concentrated to detect prion infection in the blood. Approaches can be aimed at detecting differences in the expression pattern of proteins and/or nucleic acids between healthy and diseased organisms that can allow early detection of prion before clinical signs appear. Such distinctions could be made through the use of antibodies or other molecular affinity reagents, such as peptide or nucleic acid aptamers, with high specificities for target recognition. Any methodology/technology/reagent developed under this topic could provide critical intervention measures against Prion infections. This research could develop new therapeutic agents, including antibodies that either block the conversion of PrPc to PrPsc or disrupt the molecular mechanisms of pathogenesis of TSEs after this conversion has taken place. Additionally, it may be possible to develop novel methods for removing prion from or inactivating prions in blood products and tissues in vitro, using physical, chemical, or immune mechanisms alone or in combination. These outcomes will be highly applicable to both military and civilian personnel including the animals. This research could lead not only to better diagnostics, but also to better therapeutics and prophylactic strategies.

PHASE I: Design a feasibility study for applying appropriate methods for targeting prion infection in the blood. This feasibility study should include strict enforcement measures.

PHASE II: Studies must demonstrate effectiveness of the Detection Model on prion. infection in animal model.

PHASE III: This phase should demonstrate applicability of the Detection Model for military and civilian personnel. The commercialization potential of the resulting any methodology/technology/reagent is high and is an important consideration in both the military and civilian environment. Products developed under this topic will have a strong patent potential.

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KEYWORDS: Keywords: Prion diagnostics, treatment, prevention

OSD05-H06 TITLE: The Use of Proteomics for Surrogate Markers of Prion Infection

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Identify surrogate markers or signatures for the detection of prions or prion diseases

DESCRIPTION: PrPsc is well-suited as a marker for the post-mortem diagnosis of Prion-related diseases, Transmissible spongiform encephalopathies (TSEs), because high concentrations are found in the CNS of infected animals and humans. However, from the perspective of preclinical diagnosis, the use of PrPsc as a marker is limited because its concentrations outside the CNS and, in particular, in easily accessible body fluid (e.g blood and urine) are extremely low. The detection of protease-resistant PrP-derived molecule in urine of prion-infected animals and humans has been reported (1). However, a solid routine test has not been established. Detecting TSEs before patients show clinical symptoms is an urgent priority. Thus, the search for another disease-indicating markers for early detection of TSEs other than PrPsc from easily available body fluids is utmost important.

This topic seeks the use of proteomics to identify surrogate markers for prion diseases. Proteomics is an emerging field in medical science focused on the library of proteins specific to a given biosystem, the proteome, and understanding relationships therein. This field incorporates technologies that can be applied to the body fluid and tissue in order to extract important biological information. These tools include laser capture microdissection, tissue lysate arrays and mass spectrometry approaches. These new technologies are more potent coupled with advanced bioinformatics analysis and can provide specific combinations of disease-related expression profiles that could identify the disease with much more reliability and allow us to monitor preventive strategies. The application of these tools has been assessed for the discovery of new biomarkers identification in the case of cancer patients (2 & 3). The main aim of this topic is to investigate new surrogate markers of prion diseases that may lead to new diagnostic tests and improvements in therapeutics. All responses must deliver a reasonable method for working with complex biological samples (serum, urine, biopsy, etc). Early detection of diseases is needed for military force protection initiatives. The adaptability of the platform may be powerful tool for military applications. Furthermore the importance of integrating these proteomics data outcomes with other information sources (i.e. genomic data, demographic data) should be taken into account to create a whole system delivery for diagnosis and treatment.

PHASE I: Identify, outline and design a proteomics platform to identify surrogate markers for prion infection.

PHASE II: Develop the proteomics platform and perform preliminary in vitro testing of the platform. Develop the platform as a clinical testing tool and demonstrate the utility in biological samples. Employ methodology to work with complex biological samples in a rapid multi-samples system. Demonstrate the ability of the platform to rapidly and accurately detect and identify the disease markers (specificity and sensitivity should be greater than 95%).

PHASE III: The proteomics platform will be highly applicable to the military environment including force protection. Biomarkers for early detection of prion infection are needed to best care for military personnel and their beneficiaries, and to reduce the associated health care costs. Biomarkers identified using this technology would be helpful for rapid and accurate detection of prion infectious disease. Also, it could reduce the risk of contaminating blood supplies and hospital equipment.

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2. Janssens J., Verlinden I., Gungor N., Raus J., Michiels L. 2004, Protein biomarkers for breast cancer prevention., European Journal of Cancer Prevention, 13(4):307-317.
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KEYWORDS: Proteomics, biomarkers, prion diagnosis.

OSD05-H07 TITLE: Development of a Multiplexed Point-of-Care Assay for the Detection of Infectious Agents Causing Fever in Deployed Soldiers

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Adapt state-of-the-art technology to develop a field deployable assay capable of detecting and identifying fever causing infectious agents in blood or serum samples.

DESCRIPTION:
A. Requirement: To quickly and accurately identify the pathogen causing fever in deployed soldiers. Fever is a leading cause of morbidity in deployed soldiers – the rapid identification of the pathogen causing the fever is required in order to initiate appropriate treatment and to minimize the impact of the disease on our operational capabilities. In order to minimize medical evacuation and lost-duty time, identification of the pathogen should occur as far-forward as possible.

B. Desired capability/concept of the final product: We envision a rapid, multiplexed detection assay capable of simultaneously determining (detecting and differentiating) whether a given blood/serum sample is infected with 1) malaria (any species of Plasmodium), 2) any flavivirus (e.g., dengue virus, Japanese encephalitis virus, etc.), 3) Salmonella typhi, 4) leptospirosis (any species of Leptospira), or 5) rickettsial disease (any species of Rickettsia). The assay must be rapid (<30 min), one- or two-step format, and stable (storage at 35 degrees C for 2 years). The assay should 80% as specific and 80% as sensitive compared to current gold-standard assays. The assay must be soldier-friendly (i.e., easy to operate), inexpensive, portable, use heat-stable reagents, and have no special storage requirements.

C. Dual use applications: The developed technology could be used by military forces deployed throughout the world. Local governments or regional commercial medical centers in the developing countries in this region could also use this technology to accurately and rapidly assess the threat from pathogens that cause fever.

D. Commercial applications (Spin-Off): Government or commercial medical centers throughout the developing world require cheap, easy-to-use diagnostic assays for the detection and identification of pathogens that cause fever. The development of a field-usable, multiplexed point-of-care assay for fever causing agents would provide an urgently needed device that would be commercially viable.

E. Technical Risk: There is a degree of technical risk involved in this project. There are currently no existing assays that meet the requirements outlined in this proposal -- the candidate contractor is expected to use innovation and in-house expertise to develop a prototype that meets the needs of the Department of Defense.

F. Access to Government facilities and supplies: The development of the required diagnostic assay will require support (reagents, positive-control material, etc.) from the Walter Reed Army Institute of Research (WRAIR) or the Naval Medical Research Center (NMRC) in Silver Spring, Maryland. The candidate contractor should coordinate with the COR for any required support prior to the submission of the proposal.

PHASE I: Selected contractor determines the feasibility of the concept by developing a prototype diagnostic assay that has the potential to meet the broad needs discussed in this topic. Selected contractor must coordinate with the COR for access to required reagents and positive control material from the WRAIR or NMRC. A limited supply of reagents and positive control material will be provided to the SBIR contractor (these reagents may not be sufficient to complete all work required by the contract – the contractor may have to obtain additional reagents from a source other than WRAIR or NMRC). The selected contractor provides a single lot of 500 prototype assays to the COR for initial laboratory testing at the WRAIR or NMRC.

PHASE II: The selected contractor provides up to 3 initial lots of 500 prototype assays/lot to the COR -- these initial lots will be evaluated at WRAIR or NMRC for sensitivity and specificity. Feedback regarding the sensitivity/specificity of each lot of prototype assays will be provided to the contractor – this data will then be used to optimize each subsequent lot of assays. The goal in Phase II is the development of a prototype assay that provides 80% sensitivity and 80% specificity when compared to current gold standard assays for each particular pathogen (see list of pathogens above). Once sensitivity/specificity requirements have been met, the selected contractor provides a final lot of 10,000 assays to the COR for laboratory confirmation of assay performance characteristics (sensitivity, specificity, positive and negative predictive value, accuracy and reliability) and initial field testing. Testing for performance characteristics by WRAIR or NMRC will be conducted at no cost to the SBIR contract. The selected contractor will also conduct stability testing of the prototype device in Phase II. Stability testing will follow both real-time and accelerated (attempt to force the product to fail under a broad range of temperature and humidity conditions and extremes) testing in accordance with FDA requirements.

PHASE III: The selected contractor provides 20,000 assays produced under GMP conditions to the COR. The performance of these assays will be evaluated under a variety of laboratory and field validation studies – data from these studies will be used by the selected contractor to prepare a 510(k) application to the FDA. Funding for required testing will be provided by the contractor and by the Military Infectious Disease Research Program (details on funding will need to be coordinated at the time that the Phase III proposal is prepared).

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KEYWORDS: Fever, pathogen, diagnosis, devices, multiplex

OSD05-H08 TITLE: Tool for Pharmacovigilance: for Infectious Disease, Combat Casualty Care and Biological Warfare and Chemical Defense Medications and Vaccines

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Development and application of pharmacovigilance tools to augment clinical trial safety data with public-domain post-marketing data, patient safety data, and in-house clinical trial data.

DESCRIPTION: Successful development of new biological warfare, combat casualty, and infectious disease medications follows traditional drug development life-cycle epochs ranging from preclinical discovery to large multi-center clinical trials and post-marketing safety surveillance. The principal objective of early first-in-man studies is the characterization of the safety profile that typically must be extracted from a very small number of subjects. While safety remains an endpoint of concern throughout development, DOD sponsored clinical studies rarely evaluate more than 3,000 patient volunteers in a clinical development program spanning up to ten years. However, even large Phase III studies conducted at multiple sites can fail to discover rare yet serious adverse events. To better design the clinical investigations of new treatment agents for our warfighters, information from prior studies and from similar products will facilitate the clinical trial design by providing adverse event data from similar

drugs (failed drugs or marketed drugs), thereby ensuring appropriate lab test and procedures are incorporated into the design. Detecting rare safety signals from these pre-approval studies is problematic simply due to the relatively small population of participants and the lack of prior information about specific risks. The benefits of better information about a treatment's safety are obvious. In addiction, risks are managed in light of treatment alternatives and careful monitoring of factors that affect risks; monitoring of risks and benefits is also expected of sponsors. Information derived by examining the adverse reaction experience of the population at large, as can be obtained from the spontaneous reporting databases of the WHO and FDA, can help formulate or alter future study designs and provide leads to discovery teams seeking to improve treatment alternatives. In addition, physicians can provide better medical care by assessing the risk to his patient from data obtained from the population of similar exposed patients.

DOD seeks the development and application of pharmacovigilance tools to augment clinical trial safety data with public-domain post-marketing data and DOD patient safety data.

PHASE I: During Phase I, the project is expected to identify data sources needed to provide source records to characterize safety of marketed drugs and vaccines, and to formulate a plan to transform data records into an analytic database suitable for generating hypotheses based on relationships between drugs or vaccines and events.

PHASE II: During Phase II of the project, it will implement the plan developed in Phase I, including data cleaning and other preparation needed to support data mining by DOD, and its researchers, on an ongoing basis. The principal product of the effort will be the creation of an analytic database and the associated tools required to maintain a pharmacovigilance database to assess safety of marketed and to-be-developed combat casualty, infecious diseases, and biological and chemical defense treatment agents.

PHASE III: Assist DOD in transitioning the prototype tool to use with clinical protocols conducted under the Army Congressionally Directed Medical Research program, the Military Infectious Disease Research Program, the Combat Casualty Care Research Program, and the DOD Joint Vaccine Program. The Department of Defense needs to rapidly respond to the changing needs of Force Protection. This pharmacovigilant tool would allow rapid and accurate safety signal evaluation and assessment for medical investigative products, such as drugs and vaccines, being developed for force protection. Because this tool is independent of product, it could be equally beneficial to our NATO partners and to the civilian pharmaceutical industry.

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6.http://www.who-umc.org/projects.html
7.http://portal.acm.org/citation.cfm?id=956792

KEYWORDS: pharmacovigilance, safety signal, data mining, data warehouse

OSD05-H09 TITLE: Regional Anesthesia Simulator for Training of Resident and Staff Pain Management Specialists

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To prepare a proof-of-concept, design, develop, build and demonstrate a simulation training system that will deliver didactic training in, and allow simulated performance of regional anesthesia procedures. This simulator will be utilized in the training of military and civilian health care professionals, (i.e., physicians, special forces medics, as well as allied, non-governmental organization and foreign national healthcare professionals).

DESCRIPTION: This topic falls into the category of "virtual workbench" simulator. (Though part-task mannequin-based simulators will be considered, the preference is for the smallest/lightest form factor technically feasible. It is

believed that the technology exists to allow this device to be developed as a virtual workbench.) The system should promote the acquisition and maintenance of skills in regional anesthesia techniques and provide a level of training not possible using the traditional training methods or mannequin based methods currently in use. The majority of casualties in recent conflicts have had superficial wounds or wounds of the extremities that are amenable to regional anesthesia management as a pain management measure before and after surgical intervention or as the primary anesthetic for wound care. Regional anesthesia allows provision of quality analgesia on the battlefield with minimal logistical support. Benefits include but are not limited to: simple, easily transported equipment, provision of profound, limb-specific perioperative analgesia that allows maintenance of stable hemodynamic status, reduced need for other anesthetics with resultant improved patient alertness, minimal side effects and rapid recovery. Recent experience in combat has demonstrated excellent efficacy and patient satisfaction. However, regional anesthesia training is not presently a part of basic anesthesiology training. Rather, providers must complete additional post graduate and continuing medical education training to gain the requisite skills. The clinical and logistical benefits of regional anesthesia make it reasonable for every military anesthesiologist to have access to this training. The proposed system would allow for rapid initial and regular sustainment training. Specific regional anesthesia procedures that should be addressed by the simulator (single injection or continuous peripheral nerve blocks) include but are not limited to: Superficial cervical plexus block, Axillary brachial plexus block, IV regional anesthesia, wrist block, digital nerve block, intercostobrachial nerve block, saphenous nerve block, ankle block, femoral nerve block. The performance of blocks in traumatically amputated limbs should also be addressed.

The following performance objectives should be met: 1. Simulator should provide at least visual and if possible tactile feedback consistent with the visualization and manipulation of the region of interest to include physiologic response of the region of interest to a nerve stimulator (e.g. appropriate muscles/parts of extremities move when the nerve subserving that region is stimulated, and/or the simulated patient can respond that nerve-specific sensations are felt upon stimulation depending upon the scenario). 2. Techniques for simulation of relevant physiological events (bleeding, swelling, pain syndromes) should be explored. 3. Integrate realistic modeling of local tissue surface deformation. 4. Realistic lighting simulation should be explored to simulate moist/bleeding tissue surfaces and resulting lighting effects. 5. Real-time collision processing should be explored to detect local collisions between needle and tissues. 6. Integrate a computer-based geometric model of the anatomic areas of interest that can display the different characteristics of adult and pediatric anatomy. 7. Integrate the physics processing, device tracking, multimedia, and graphics rendering that will be applicable to complex real-time environments. 8. Allow for utilization of synthesized imaging modalities that would be available to the anesthesiologist in a field environment. (this should be able to be adjusted to specific echelons of care, e.g. no imaging; x-ray and/or ultrasound only; or addition of fluoroscopy and CT to resemble a general hospital or hospital ship.) Include 3-D transparent views for demonstrating real-time position of needle, tissues and injected/infiltrated medications. 9. Of particular interest are technologies and techniques that present the user with multiple patient conditions and complications that might be encountered during management. 10. Management should be based on clinical protocols developed and accepted by credentialed pain management specialists. 11. Cases and management should be based on embedded metrics for performance assessment and training. 12. User interface should contain a module that allows the teaching, rehearsal, testing and results tracking of the user. 13. Didactic content should include a SCORM-compliant browser-based didactic curriculum that can run separately or simultaneously with the simulator. Content should encompass peri-procedural aspects of regional anesthesia management, including patient preparation, local anesthesia, indications and contraindications, complications, and patient transport. 14. Simulation interoperability should be addressed such that the simulator can be integrated with existing and planned DoD training systems.

PHASE I: Phase I will develop a feasibility concept and plan for developing and /or applying various innovative simulation technologies to the performance of regional anesthesia . Performance objectives listed in the topic description should be addressed.

PHASE II: Phase 2 will develop and demonstrate a working functional prototype of the procedure simulator. The interface platform will enable the integration of individual patient cases. The simulation should include management in adults and children to include presenting an array of complications. At a minimum, the regional anesthesia management of extremity wounds and traumatic amputations of the extremities should be addressed. The simulator and completed scenarios should be assessed for validity through comparison with existing regional anesthesia training methods.

PHASE III DUAL-USE COMMERCIALIZATION: The focus will be on commercializing a training system that is fieldable in both the military and civilian arenas. The training can be expanded for other military and civilian relevant pain management procedures in other anatomic regions (e.g. celiac plexus blocks, radiofrequency and cryo-ablation). In the future the system should be capable of allowing providers to train for patient-specific cases (e.g. utilizing imaging data from actual patients)

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Liu, A., Cotin, S., et al MICCAI 2003 Tutorial: Simulation for Medical Education,
http://www.simcen.org/miccai2003/index.php

KEYWORDS: regional anesthesia; field surgery; combat casualty care; training; simulation; trauma; military medicine; anesthesia skills training; medical modeling and simulation

OSD05-H10 TITLE: Mechanisms for Hands-Free Point of Care Data Entry in Combat Environments

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Design, develop, and integrate a hands- and eyes-free interface that allows military healthcare providers to capture patient encounter data while in a combat environment.

DESCRIPTION: On the battlefield, military medical personnel face a unique array of challenges that can affect their ability to deliver quality care. Documentation of patient encounters, one of the most important components of quality care, is often the first to suffer in the noise and chaos of a combat environment. The importance of capturing clinically meaningful data at the point of care cannot be overemphasized, not only because of its role in the care of individual patients, but also because of how such data contributes to an overall picture of troop health and readiness.

The military and its research partners have already developed effective mobile tools for collecting data at the point of care, but so far most of these rely upon entering data into electronic forms, usually via a pen interface or standard keyboard, or even by means of a voice interface. Despite significant technological innovations in this arena, ranging from noise-canceling microphones to systems for the remote monitoring of vital signs, a fully integrated solution is still lacking, and critical encounter data from the field is not always reliably captured.

The missing link is a technology that enables the provider to capture encounter data as accurately and completely as possible, while at the same time frees his or her hands and eyes for the more urgent tasks of patient care. Candidate technologies would likely rely on a voice-enabled interface that would not only be hands-free, but would also eliminate the need for a user's simultaneous visual attention on a screen. It would also be critical that the current effort focus on integration with existing military systems that are part of the Theater Medical Information Program (TMIP) infrastructure.

PHASE I: Conduct a market analysis and literature review of relevant technologies, and develop a concept design and integration strategy for the interface to be developed.

PHASE II: Develop and demonstrate an integrated prototype that can function under field conditions.

PHASE III DUAL USE APPLICATIONS: The final integrated solution would be applicable to a range of military and civilian applications, such as in disaster relief and other emergency situations.

REFERENCES:
http://www.tricare.osd.mil/peo/tmip/default.htm
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KEYWORDS: theater, operational medicine, combat, informatics, health surveillance, longitudinal health record

OSD05-H11 TITLE: Wearable Biomechanical and Physiological Monitoring Apparatus for Amputees

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop and demonstrate a Wearable Biomechanical and Physiological Monitoring Apparatus for Amputees (BPMAA) system capable of gathering and analyzing data to assess biomechanical status and energy balance for up to 24 hours.

DESCRIPTION: A significant number of Soldier amputees are being fitted with prosthetic devices and being rehabilitated for potential return to active duty. This creates a number of challenges for the medical and operational communities as well as the amputee in regard to functional ability, energy expenditure (EE), and biomechanical constraints. Many of these challenges may be overcome though wearable technologies and data analysis techniques. Development of such technologies should assist in ascertaining the cause, indicating the magnitude, and identifying potential interventions for a multitude of factors. For instance, these technologies should evaluate the amputee's ability to maintain an appropriate energy balance by determining if EE is commensurate with energy intake. Additionally, they should be able to record and monitor episodic balance disturbances and optimally resolve which component of balance (visual, equilibrative, proprioceptive, or kinesithetic) creates the greatest deficit. These technologies should also be able to incorporate movement analysis with the potential for feedback for integrative prosthetics (human in-the-loop artificial proprioception and / or servo-loop). They should be able to monitor mechanical efficiency on-line to include information on the ratio of metabolic cost to mechanical work during gait and fine motor activities. Finally, they should relate military occupational specialty demands with amputee performance and capacity.

Assessment of EE is important in terms of understanding the energy requirements of daily living and Soldier tasks. While EE can be measured in the controlled laboratory, there is not currently an accurate, practical means of gathering this data in an operational environment. Additionally, in order to optimally understand and correct energy imbalances in the amputee, measures of EE need to be paired with relevant biomechanical analyses. Measurement of EE in the amputee is also complicated by factors such as the site/degree of amputation, whether the prosthetic device is on or off, and asymmetry of body movements. The challenge is to develop a low-power, compact, device that can account for these various factors and assess biomechanical and energy parameters simultaneously.

We seek a novel BPMAA design that can: (a) utilize accelerometry, GPS and/or other relevant sensor technologies to assess EE, (b) provide extended monitoring (i.e., 24 h or more), (c) provide high correlations with rates of oxygen consumption, mechanical efficiency, and rate of perceived exertion, (c) monitor status in operational and non-operational environments (d) accommodate the entire amputee population regardless of site or degree of injury (e) provide monitoring of Soldiers across the spectrum of functional recovery; post-surgical to high level recovery (f) account for differences in EE due to asymmetric movement patterns (g) differentiate function independent of use (or type) of prosthetic device (h) avoid a negative impact on energy expenditure due to size.

PHASE I: Identify the technologies or technical path to be used to capture the relevant data. Specifically, provide a high level system architecture to include sensor type (e.g., accelerometer, GPS, rate gyros, etc.), sensor location(s), sensor communication (wired, wireless), data management (e.g., full disclosure with post hoc analysis, distributed algorithms and processing, etc.), and system data storage capacity. Clearly define the useful outputs envisioned and

their utility to the various customers (researcher, clinician, patient). Identify planned use of commercial as well as custom elements. Phase I should include a proof-of-concept demonstration of the proposed approach.

PHASE II: Finalize design concept to meet the objectives outlined in Phase I and develop a prototype system for demonstration. This device should be suitable for laboratory testing and field trials. This work effort should also include a plan for ruggedization and packaging of the system to support future operational deployment. A prototype system that has been tested and evaluated prior to delivery is preferred.

PHASE III DUAL USE APPLICATIONS: Provide at least 10 prototype systems that meet the objectives outlined in Phase II. The Phase III effort will include field trials of the BPMAA system under various working and training conditions including structured Soldier performance tasks. The offeror should aggressively pursue civilian BPMAA applications. The intent is to provide metabolic and biomechanical data for various clinical populations. This would have applicability to individuals with obesity, balance deficits, central and peripheral neuropathic conditions, as well as those at risk for osteoporotic fractures. This technology is expected to have relevance to early identification of neuropathologic conditions such as Parkinson's disease. A robust system would also have the potential to be a useful part of prosthetic design and integration with the body's natural systems.

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KEYWORDS: amputee; prosthetics; metabolic rate; mechanical work; ambulatory monitoring

OSD05-H12 TITLE: Portable Pulmonary Injury Diagnostic Device

TECHNOLOGY AREAS: Biomedical, Human Systems

OBJECTIVE: Enable corpsman to diagnose existence of a pneumothorax at the point of wounding in conscious and unconscious combat casualties.

DESCRIPTION: About 15% of combat injuries sustained during conventional land warfare will involve the thorax. The spectrum of these injuries ranges from tiny superficial fragment wounds to grossly mutilating blast injuries. Interthoracic wounds causing a pneumothorax are critical to identify for optimal casualty treatment; however, signs and symptoms are difficult to diagnose on the battlefield due to the inability to discriminate breath sounds.

A non-invasive diagnostic tool available to first responders for detecting pneumothorax in the presence of high ambient noise would improve casualty treatment on the battlefield. Current competing technologies are Spiral Computerized Tomography, Fluorescent Bronchoscopy and X-ray Tomography, Ultrasound, and Auscultation and Percussion examination. However, these technologies are not desirable for first responder usage because they are not portable/field deployable, use suboptimal frequencies, and/or require medical training and clinical experience to be effective.

This effort will develop a handheld device for primary diagnostics of interthoracic injuries in environments which prevent the use of conventional clinical methods. The technology should be based on percussion examination principles and the device should be low cost, low frequency, and automated with a clear and easy to understand readout.

PHASE I: Develop physical and mathematical models of contact source low-frequency sound radiation; Compute numerically acoustic frequency spectrums of radiated and received signals; Study various types of receivers contrasted with the measurement of the impedance on the load circuit of the amplifier; Design a table top device for objective percussion and arrange experimental measurements on model tissues.

PHASE II: Investigate resolution capabilities of percussion images; Provide preliminary clinical tests of the device. Produce a working prototype.

PHASE III DUAL USE COMMERCIALIZATION: Produce a user-friendly device which can be used by battlefield first responders as well as civilian emergency crews and hospitals. Use if this device could also have the potential of becoming a part of routine medical diagnostics.

REFERENCES: V.D. Svet et al. "Spectral Analysis of Acoustic Vibrations on the Surface of the Human Body", Acoust. Physics. 41, 50-58 (1995)

KEYWORDS: pneumothorax, diagnostics, pulmonary injury, percussion examination principles

OSD05-H13 TITLE: Vertical Linear Accelerator for Dynamic Visual-Vestibular Acuity Health Status Evaluation and Desensitization Training

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: To provide a human-rated linear motion device with chair mounted projection system capable of delivering visual acuity screening stimuli during vertical oscillations.

DESCRIPTION: Several military platforms induce significant amounts of vertical linear acceleration. Functional performance on these service platforms requires the visual suppression of vestibular (inner ear) ocular reflexes in order to view platform-fixed displays. Undetected visual-vestibular pathology or injury during deployment increases risk of spatial disorientation related mishaps, and/or decreased performance due to motion sickness related symptoms. The ability to provide adequate health status evaluation of this important function has been traditionally limited to subjective ratings by non-specialist health care professionals. A computer-controlled motion device that can induce vertical linear motion will provide more systematic and sensitive heath status evaluation that can be deployed and conducted by non-specialists. The incorporation of visual acuity tasks will ensure the metrics will provide functionally relevant assessment of risk. In addition to screening exams, this vertical motion device can be employed as a rehabilitation tool. Evidence for this comes from the Royal Air Force who report repeated exposures to vertical linear motion as a successful desensitization tool for chronically motion sick aircrew.

PHASE I: The proposal for Phase I should identify the review of different linear motion technologies that could provide a field-based vertical motion device covering functionally relevant frequency (0.1-2.0 Hz) and amplitude (0.1 – 1G) range. The Phase I study should also include the development of a lightweight visual projection device that can be mounted to the vertical oscillator and provide visual optotypes (e.g., Landolt C) covering a wide range of sizes (logMAR -0.3 to 1 in 0.1 steps) at near (0.5m) viewing distances. During Phase I, the visual projection system should be prototyped and tested with existing motion devices to evaluate both acuity and desensitization protocols.

PHASE II: In Phase II, the vertical motion device development should be completed following critical design reviews with the technical staff. This device will undergo feasibility testing for both screening and desensitization applications. To accomplish this, the device will be installed at a military base with other state-of-the-art vestibular test capabilities and with access to military personnel undergoing a motion sickness related desensitization program.

PHASE III: During Phase III, the private sector applications of this device will be explored with installation of a second unit in a neurotology clinic where diagnostic performance can be compared with other comprehensive balance function screening tools, and the device can be implemented as a tool for vertigo and motion sickness desensitization.

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KEYWORDS: vestibular, acuity, balance, otolith, assessment

OSD05-H14 TITLE: MedNet: An Agent Based Medical Treatment Support Tool

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: In the combat environment, the ability to rapidly diagnose and treat a wide range of injuries is critical. With the exception of the 'classic' injuries with which most service members are familiar, successful care requires rapid decision making skills. Yet, in the combat environment, which is replete with external stressors, such abilities can quickly degrade. A comprehensive tool for offsetting this decay would provide a much needed counterpoint to this decay.

DESCRIPTION: MedNet will be composed of 3 elements. The first element, MedNet Database, will be a multi-modal searchable database of medical case studies, searchable using either speech descriptions or scanned images of the injury, for appropriate treatments. Additionally, this database will support real-time annotation, allowing medics to share unique experiences treating a given injury, thereby serving as a medical lessons learned repository. The field hardware supporting this database should be ruggedized, lightweight and contain its own internal power source. The second element, MedNet Tag, lightweight, self-contained device, forming part of the Medic's toolkit, that can be quickly placed on the injured Warfighter to reliably capture critical health status information including: Temperature, Heart Rate, Blood Pressure and other triage relevant information in a tactical environment. Data will be relayed, in real time, to the MedNet Database through an independent communication capability, and will not be dependent on existing military communication infrastructures. The MedNet Database will also provide another source of information to be integrated with that being developed through the MedNet Database and Theater Medical Information Program. The final element, MedNet Grid, will be an agent based architecture which will assist medics in moving through a diagnosis tree, providing cues as necessary to enable the medic to more quickly arrive at the correct treatment plan. The primary role of the Grid is to synthesize information and to then provide a small set of potential diagnoses and treatments, with appropriate probabilistic weightings attached to each. Importantly, the Grid will not replace the medic as decision maker. Rather, by offloading a portion of the processes necessary for arriving at decision making, it should enable the medic to perform his actions more quickly and effectively. As more information becomes available, the confidence weighting for each diagnosis and treatment, as well as the number of such options, will be reduced. This architecture should allow for communication with other similar architectures; like the TMIP Expeditionary Framework to both enhance the reliability of the decision support system, as well as to assist in the development of a global combat medicine grid.

PHASE I: Conduct feasibility assessment for technologies underlying the development of the MedNet system. The MedNet Grid forms the hub of this effort, so particular attention should be paid to determining the elements comprising this, including the underlying algorithms for synthesizing data and developing relevant weightings. This Phase should result in a detailed framework and timeline for integrating these technologies, as well as a test plan for assessing their utility in the field.

PHASE II: Develop the prototype MedNet system, performing iterative Usability assessments during each build, concluding with a technology demonstration of the MedNet tool in the field.

PHASE III: The MedNet tool will provide much-needed support to both DoD users as well as First Responders at the local and state levels. MedNet will also provide Federal agencies such as FEMA and DHS with an additional tool for their disaster management toolkits.

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KEYWORDS: Triage, Database, Combat Medicine, Diagnosis and Treatment, Agents, Medical Monitor.

OSD05-H15 TITLE: Smart Hemodynamic Monitoring System for Critical Care Air Transport Team (CCATT)

TECHNOLOGY AREAS: Biomedical

OBJECTIVE: Develop a system that analyzes patient hemodynamic information in order to act as an “intelligent assistant” to the CCATT team during the monitoring or resuscitation of a critically injured casualty.

DESCRIPTION: In past wartime scenarios, severely wounded casualties were generally not air evacuated out of the area of conflict until they became well stabilized. The successful development of the Critical Care Air Transport Team (CCATT) concept, initiated in 1997, now allows the transport of critically ill patients during long flights to major medical centers. A CCATT team typically consists of a Critical Care Physician (Surgeon, Anesthesiologist, Emergency Physician, or Pulmonologist), a Critical Care Nurse, and a Cardiopulmonary Technician. The patients they deal with are generally casualties with serious wartime traumatic injuries of various types. They must be able to transport up to six critically ill patients for 10-12 hours by air, in various aircraft including the C-17 Globemaster III, C-130 Hercules, KC-135 Stratotanker, and C-141 Starlifter. Typical parameters monitored include cardiac rate/rhythm, end-tidal CO2, capillary pulse oximeter readings, and invasive or non-invasive blood pressure measurements. The teams currently use a Pro Pack 206EL to track this information.

The purpose of this topic is to develop an “intelligent assistant” to the treating physician to assist with a critically ill but stabilized patient in flight. This system would utilize various data sources such as direct feeds of hemodynamic data and manual entries of appropriate parameters by the team, process the information to determine hemodynamic stability and autonomic state, and give treatment suggestions to the team leader. These suggestions would include such items as amounts of fluid boluses, blood transfusions, and a variety of inotropic agents. The system will not control anything directly, but will give suggestions to the CCATT team that may be over-ruled. Furthermore, the system should be able to interpret changes in hemodynamic parameters in response to the treatments given and incorporate those into its analyses.

The system (without attached leads) should weigh no more than 20 pounds, no more than approximately 12 X 12 X 12 inches and be attachable to an IV pole or clip to the side of the NATO standard stretcher. Smaller/lighter devices are always desirable. The device must be usable in high- or low-light conditions, high (100 degrees F) or cold (0 degrees F) environmental temperatures, and rainy or sandy conditions. Physically, it must be able to operate in a high noise environment (100 dBA), during moderate vibrations, at decreased atmospheric pressures up to10,000 feet altitude, and not interfere with standard aircraft communication frequencies. The primary power source will be 120 V AC, 60 Hz, with a backup battery system able to maintain its functionality for 120 minutes without external power. It must be compatible with the Pro-Pak 206EL system. Parameter alarm signals must be adjustable by the operators depending on the scenario: auditory (silent to loud volume) and/or visual (off to bright).

PHASE I: Consider various concepts/designs, select one, demonstrate its feasibility, and show that the prototype will be small/light, will have the resilience to function in austere conditions as described above, can effectively monitor hemodynamic parameters, and can utilize logical decision trees to give appropriate treatment recommendations to the CCATT team.

PHASE II: Build a prototype and arrange/perform testing to demonstrate readiness for field operations, FDA approval, and certification for in-flight use.

PHASE III DUAL USE COMMERCIALIZATION: The goal is to develop a hemodynamic "intelligent assistant" for the CCATT team in austere conditions and in-flight. Dual use applications of this device or modifications include Intensive Care and Emergency Departments as well as general anesthesia use in the operating room.

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KEYWORDS: Hemodynamic, monitoring, critical care, CCATT, shock