Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA))
Defense Health Program (DHP)
12.2 Small Business Innovation Research (SBIR)
Proposal Submission Instructions

Introduction

The OASD(HA) Defense Health Program SBIR Program is sponsoring topics in the biomedical technology theme in this solicitation.

The Army and Navy are participating in the DHP SBIR Program in this solicitation. The service laboratories act as our OASD(HA) Agent in the management and execution of the contracts with small businesses. The service laboratories, often referred to as a DoD Component acting on behalf of the OASD(HA), invite small business firms to submit proposals under this Small Business Innovation Research (SBIR) Program Solicitation. In order to participate in the DHP SBIR Program this year, all potential proposers should register on the DoD SBIR website as soon as possible, 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 SBIR 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 of 25 pages. 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 website. The submission site does not limit the overall file size for each electronic proposal; however, there is **a 25-page limit**. Please note: 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 your proposal 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 DHP 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 DHP 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 DHP 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 over a period not to exceed six months, with a dollar value up to $150,000. We plan to fund 3 Phase I contracts, on average, and down-select to one Phase II contract per topic. This is assuming that the proposals are sufficient in quality to fund. Proposals are evaluated using the Phase I evaluation criteria, in accordance with paragraph 4.2 of the DoD Program Solicitation. 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 a period generally not to exceed 24 months (subject to negotiation), with a dollar value up to $1,000,000. 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, may 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 DHP SBIR Program has a Phase II Enhancement Program, which provides matching SBIR funds to expand an existing Phase II contract that attracts investment funds from a DoD acquisition program, a non-SBIR/non-STTR government program or Private sector investments. Phase II Enhancements allow for an existing Phase II DHP SBIR contract to be extended for up to one year per Phase II Enhancement application, to perform additional research and development. Phase II Enhancement matching funds will be provided on a one-for-one basis up to a maximum $500,000 of SBIR funds. All Phase II Enhancement 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 Enhancement contract modification. The funds provided by the DoD acquisition program or a non-SBIR/non-STTR government program must be obligated on the DHP Phase II contract as a modification just prior to or concurrent with the DHP SBIR funds. Private sector funds must be deemed an "outside investor" which may include such entities as another company, or an investor. It does not include the owners or family members, or affiliates of the small business (13 CFR 121.103).

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 has 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 and awarded contract.

Contact with DoD

General informational questions pertaining to proposal instructions contained in this solicitation should be directed to the Topic Authors and Points of Contact identified in the topic description section. 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; however, to obtain answers to technical questions during the formal Solicitation period, please visit http://www.dodsbir.net/sitis. 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).

DHP SBIR 12.2 Topic Index

DHP SBIR 12.2 Topic Descriptions

DHP12-001 TITLE: Junctional and Non-Compressible Hemorrhage Control Training System

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: To develop a simulation-based training system to assist in teaching and training junctional and non-compressible hemorrhage control. The primary target is existing US Army / DOD military medical special operations training programs, but a secondary target could be other government agencies upon coordination with the government topic manager. The system could also have application to medical training programs in the academic and private sectors. The training audience is "soon-to-be-deployed" medics. The field of point of injury care is dynamic, but the simulation technologies applied to improve trauma training are nascent. So, we seek the development of an innovative, adaptable, and expandable trauma training system.

DESCRIPTION: Deployed military medics and non-medic soldiers, especially those with non- medical functions, are driven on the battlefield to manage significant junctional and non-compressible hemorrhage that, until recently, have not been treatable. New adjuncts have been developed, e.g., Combat Ready Clamp (CROC) and Abdominal Aortic Tourniquet, but suitable training systems have not. As a result, both medics and non-medic soldiers may be unprepared to use them proficiently. Also, medical skills are prone to deteriorate during deployment. Thus, both the US Army and other DOD medical training programs have a need to rapidly refresh skills of soldiers and soldier medics who are going to, and returning from, forward based assignments. Junctional and non-compressible hemorrhage control is a prime example of traumatic injuries that (1) are rarely seen in non-combat situations and, therefore, (2) difficult to train for.

This opportunity focuses on developing and assessing this junctional and non-compressible hemorrhage control training system to determine its effectiveness for training and use in demanding military medical training environment(s). The training system must support and respond to non-specific mechanical pressure. This training has a direct impact on the care of our military personnel, and the criteria for success are weighted toward systems demonstrating the ability to assist the staff to accomplish their mission.

We seek a system that:

- is based on established educational objectives
- includes metrics upon which to judge proficiency performance
- supports practice of both cognitive and psycho-motor skills required of medics
- presents multiple trauma cases / scenarios
- tests the cognitive and psychomotor skills of trainees at the beginning of training
- identifies deficiencies in cognitive and psychomotor capability
- tests the cognitive and psychomotor skills of trainees at the conclusion of training
- develops a training program to correct them prior to deployment
- assesses the training effectiveness of the system
- results in minimal negative impact, e.g., time, disruption, resources, of the training staff
- improves the quality of cognitive and psychomotor training, to teachers and/or students
- improves the efficiency of cognitive and psychomotor training, to teachers and/or students
- equals or reduces the cost of cognitive and psychomotor training, to teachers and/or students
- addresses virtual mentoring capability with potential to reduce time required by instructors and students
- is SCORM-compliant
- employs open architecture principles

Required: Final product must address junctional and non-compressible hemorrhage control at inguinal injury sites, pelvic injuries, e.g., groin injuries, and axillary injury sites.

Optional:

1. Hemorrhage control including target abdominal target application points, e.g., umbilicus.
2. Team training system that includes training for all members of a maneuver element, soldiers and medics.

PHASE I: Perform a feasibility study and analysis and develop a concept including discussion of how the system could be implemented. Identify the innovative technologies and approach proposed, technical risks of the approach, as well as the costs, benefits and schedule associated with development and demonstration of the prototype. Identify minimum system requirements and development tools. Demonstrate the foundational technology for simulation based junctional and non-compressible hemorrhage control training.

PHASE II: Demonstrate the prototype system's capability to train for multiple junctional and non-compressible hemorrhage control scenarios. Validation of the proposed junctional and non-compressible and Non-Compressible Hemorrhage Control Training System is mandatory. Data from these studies will need to be provided, analyzed, and presented in the final report. Report data obtained as a result of the training assessment. In the marketing plan section of the Phase II proposal, include recommendations for effective implementation and estimates of resources required to operate, maintain and sustain the system into the future.

PHASE III: This capability is expected to result in a system with military and civilian wide application to train to proficiency both the cognitive and psychomotor skills necessary to treat junctional and non-compressible hemorrhage.

REFERENCES:
1. Simulation in critical care and trauma education and training. The Surgical Patient. Current Opinion in Critical Care. 10(5):325-329, October 2004. Hammond, Jeffrey

2. Surgical Education in the New Millennium: the Military Perspective. Surgical Clinics of North America, Volume 84, Issue 6, Pages 1453-1470. C. Bowyer

3. Training Physicians for Combat Casualty Care on the Modern Battlefield. Journal of Surgical Education, Volume 64, Issue 4, July-August 2007, Pages 199-203. V. Sohn, L. Runser, R. Puntel, J. Sebesta, A. Beekley, J. Theis, N. Merrill, B. Roth. R.Rush Jr.

4. Development and Evaluation of the Advanced Trauma Operative Management Course. J Trauma. 2003; 55:471–479. L. Jacobs, K. Burns, J. Kaban, R. Gross, V. Cortes, R. Brautigam, G. Perdrizet, A. Besman, O. Kirton

KEYWORDS: Medical Modeling and Simulation, MM&S, Trauma Surgery, Trauma Training, Predeployment Training

DHP12-002 TITLE: Integrated Sensor Technology into Synthetic Anatomical Training Models for Objective User's Performance Measurement

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: To accelerate the integration of advanced sensor technology into synthetic mannequins to facilitate objective measurement of user metrics during both training and education activities. At the end of Phase I, a proof of concept must be demonstrated and at the end of Phase II an integrated prototype (Beta) must be developed and demonstrated.

DESCRIPTION: Mannequins are currently a common tool for medical training and education. Many of these have a hard exterior cover and lack adequate and/or appropriate modeled internal anatomy and thus may not even be considered for open surgical procedural training and/or laparoscopic / endoscopic procedural training. Although these existing mannequins are functionally capable of objectively measuring a user's actions, this functionality is not adequate for tracking the performance of open procedures. In some cases, the space requirements for the sensor and

communication apparatus prevent the user from performing other procedures entirely. Anatomically appropriate synthetic models have been developed and some of these have different tissue properties and may possibly serve the open and laparoscopic surgery community. The structure of these synthetic models allows trainees to dissect, cut, suture, and potentially perform a broader-range of tasks than are currently available on most commercially available mannequin(s). Mannequins which incorporate synthetic models representing a variety of tissues and/or tissue planes that are currently under development require further functional testing and validation and most still need an expert to review the novices actions subjectively. One effort that could accelerate this validation process would be the integration of advanced sensor technology to track and report on user manipulation of the specific tissues and connected with the overall systemic model. Existing advanced sensor technology is sophisticated enough to allow for the integration of embedded sensors into these mannequins/models to facilitate the measurement and reporting of targeted metrics. The integrated model as a whole must be reusable and have a high degree of repeatability of measurement. The sensors employed must provide for economical use in repeated training exercises either through high quality, durable components or low cost replaceable ones. The overall design must support repeatability of measurement in either case. The integration of the sensors with the tissues must detect dissection of tissue planes, incisions into/through tissues, and suturing (approximation) of the modeled anatomy to name a few. In addition, the advanced synthetic mannequin should replicate as much of the systemic human physiological response system as possible (i.e. changes at the tissue level have systemic affects that should be represented. Sensors implemented at the tissue level need to be integrated with other sensors and communicate data to and from other systemic sensors to measure and communicate data and information such as blood pressure, pulse, respiratory rate, stroke volume, tidal volume, pCO2, renal output, and glomerular filtration rate to name a few to the end user. The goal is to provide as realistic of a human response to interventional procedures on the synthetic mannequin as possible while also providing objective measurement of user metrics during both training and education activities.

PHASE I: Deliverable at the end of Phase I: a proof of concept for integrating advanced sensor technology with the synthetic tissues/organs demonstrating the ability to detect several different parameters including (no particular order) 1) force(s) exerted on the tissue, 2) direction(s) the force(s) applied, 3) cutting or tearing of tissue(s), and 4) forces for approximation of tissue. Must provide preliminary data relevant to the robustness and repeatability of measurement of the sensor systems and the synthetic tissue. In addition to the monthly reports and final reporting requirements, an initial concept design for an integrated system must be delivered as well. A Review will be held around the 5th or 6th month at the government site Fort Detrick, Maryland to present and demonstrate the proof of concept developed and results obtained to date. Suggested alternates to sensors used during Phase I as well as suggested alternate bio-materials used for synthetic tissues need to be considered as a part of the research.

The Phase I proposal must include projected concept and develop key component technological milestones, have a preliminary methodology on how analysis of the predicted performance of both the sensors and the synthetic tissue in addition to items such as working hypothesis, clinical impact, military impact, technical tasks, research methodologies supporting the hypothesis, and statement of work. No trials/studies needing Institutional Review Board (IRB) during Phase I will be accepted.

PHASE II: At the end of Phase II, it is expected that a fully integrated prototype system (i.e. integration of sensors, synthetic material with properties mimicking tissue, and software) be demonstrated and the demonstration is included as a final project deliverable (i.e. presentation at the government site Fort Detrick, Maryland). This integrated prototype system must provide sensing capabilities at both the tissue and system levels and provide the end user with objective data regarding the performance of the trainee. Examples of sensing capabilities are, but not limited to (and in no particular order), 1) force(s) exerted on the tissue, 2) direction(s) the force(s) applied, 3) cutting or tearing of tissue(s), 4) approximation of tissue, 5) occlusion and the release of occlusion of tissue, 6) application of energy onto the tissue, 7) multiple tools (hands / fingers can be included as “tools” applied to the tissue (such as the concept of retraction) to name just a few, and 8) measurement of “fluids” within the vasculature to name a few.

Preliminary validation of the tissue level sensor and synthetic model is mandatory: this would include items, but not necessarily limited to, detection of stretch and how much tension and distance is used on the tissue, detection of tissue cut and percentage cut (note, need to detect partial tissue cuts), tissue approximation and how much tension was placed on the tissue during approximation, and if tissue has been occluded (including partial occlusion) and release of occlusion. Validation at the systemic level (refers to something that is spread throughout, system-wide, affecting a group or system such as a body) is optional. Data from these studies are an anticipated outcome of Phase II and data should be analyzed, summarized, and presented in the final report.

At the end of Phase II it is also expected that preliminary specifications on synthetic tissue model are provided, and sensor specifications are outlined. Preliminary data regarding robustness, reliability, accuracy, and repeatability is optional as a delivery at the end of Phase II. Estimated cost for production of prototype based on costs of sensors, synthetic tissues, other materials and supplies, labor, and overhead required to produce the prototype be provided as a deliverable. Descriptions of preliminary estimated product life and robustness of synthetic tissues and sensors should be provided, and a concept of the overview of maintenance should be included in the final report.

Phase II should also include a preliminary evaluation by Subject Matter Experts (SMEs). These SMEs should not have been a part of the requirements and development and should serve only in the evaluation portion. These SMEs are not required to be military and/or government, but need to be in good standing with their respective organization and professional society. Evaluation should include clinical relevance as well and may include content and/or construct methodologies. Summary and analysis of data needs to be included as a deliverable.

The Phase II proposal should include a commercialization plan/strategy, including letters of support or agreements if applicable. This commercialization plan should include analyses of customers (types and size), market opportunities and value, cost estimate of the unit for production and for sale, and projected company's sales, revenues or operating loss.

PHASE III: A fully robust, ergonomic, cost-effective, manufactured commercialize product should be developed. Manufacturing capabilities and scale up plans provided. Test results on robustness, shipping, electrical safety testing, accuracy, consistency, and repeatability should be included. Specifications of manufactured product as well as manufacturing process need to be prepared and finalized. Materials, material properties, and conditions under which product may be shipped and stored are needed.

REFERENCES:

1. Bada, A., Birg, A., Henson, A., Narain, A., Nye, C., Summers, N., Weismiller, J., Physical Simulation Training Model for Suturing Blood Vessels, (2009). University of Tennessee Honors Thesis Projects.

2. Coles,T.R., John, N.W., and Caldwell, D.G., Investigating Augmented Reality Visio-Haptic Techniques for Medical Training, Thesis Submitted in Candidature for the Degree of Doctor of Philosophy at Bangor University, Wales, January 2011.

3. Durham, C. & Alden, K. (2008, April). Enhancing patient safety in nursing education through patient simulation. In Patient Safety and Quality: An Evidence-Based Handbook for Nurses (Chapter 51).

4. Issenberg SB, McGaghie WC, Petrusa ER, Lee Gordon D, Scalese RJ. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. Med Teach. 2005 Jan;27(1):10-28.

5. Lipomi, D., Vosgueritchian M., Tee, B.C.-K., Hellstrom S.L., Lee, J.A., Fox, C.H., and Bao, Z. Skin-like Pressure and Strain Sensors based on Transparent Elastic Films of Carbon Nanotubes. Nature Nanotechnology. 6: 788-792, 2011.

6. Liu, A., Bhasin, Y, Bowyer, M, A haptic-Enabled Simulator for Cricothyroidotomy, Medicine Meets Virtual Reality, 2005.

7. Matson, J. Sensors and Sensibility: Flexible Pressure Detectors Could Innervate Artificial Skin, Scientific American, 13 September 2010 (http://www.scientificamerican.com/article.cfm?id=electronic-skin) .

8. Pott, Leonard, Goldstein Scott, Emergency Surgical Airways, Tracheotomy Management: A Multidisciplinary Approach, Chapter 14, pp 51-61.

KEYWORDS: Synthetic model, bio-synthetic model, modeling, simulation, training, education, sensors, metrics, systemic sensing

DHP12-003 TITLE: Anatomic 3D Synthetic Tissue Printer for Medical Training

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Create a multi-substrate 3D printer with the ability to render high-fidelity anatomically accurate synthetic physical tissue models that can be used for anatomy, trauma and surgical training purposes. It is desired that such simulated tissue consist of multiple substances with varying physical properties, so that bone, muscle, vessels, skin and adipose or organ tissue can be simulated.

DESCRIPTION: As part of a strategy to lower costs and reduce the use of animal and human cadaveric tissue, this SBIR intends to develop 3D printing technology so that anatomically accurate, multi-substance human tissue analogues can be produced for training purposes. The printer should be able to produce several simulated types of tissue and deposit them in mixed format; i.e., a sample of printed tissue could include hard bone as well as compliant muscle, skin and major blood vessels and perhaps empty spaces within that substrate. If such technology were possible, a wide variety of human anatomy sections could be printed on demand. These simulated anatomy sections could be used for surgery rehearsal, visualization, procedural training and other uses. The actual printed substrates should ideally not be actual biological tissues, but rather materials that simulate their physical properties.

PHASE I: At the end of Phase I it is expected that a proof of concept of a 3D printer be demonstrated for multi-substrate deposition, including detailed data on performance of the concept and identify anticipated performance of a more sophisticated working prototype. It is expected that appropriate stimulants be created and tested for bone, muscle, adipose tissue, integument (vessels or tissue planes), skin and possibly organs. Plans for software to be used in the Phase II effort, if the company is selected, should be elucidated.

The Phase I proposal must include proposed concept and identify key component technological milestones, have a preliminary methodology on the predicted performance of the printer and printing substrates in addition to a working hypothesis, research methodologies supporting the hypothesis, technical tasks, clinical impact, military impact, and statement of work. The Phase I proposal must also include a target end-consumer cost for the printer if it were to be successfully developed. Similar cost estimates, with practical examples, must be provided for consumables needed to produce anatomical sections. Anticipated resolution must be specified.

PHASE II: At the end of Phase II it is expected that a working prototype system will be demonstrated. The working prototype must work with multiple substrates and effectively produce printing outputs that contain at least three types of tissue and empty space areas. The task of creating effective tissue planes (including major vessels) must be definitively addressed. Description of plans, if any, to colorize tissue stimulant materials during printing need to be included in the deliverable

Phase II must contain a validation study that examines simulated anatomy output for use in a medical training setting. In addition, the Phase II system must include software tools and anatomy data to allow users to produce a variety of simulated tissue sections. The ability to produce printed tissue output from data of CT and MRI scans is desired. A robust prototype, including 3D anatomy data and consumables, must be delivered for independent testing. Testing of the prototype needs to be performed by an organization that has not participated in the requirements or development. Summary and analysis of data needs to be provided as a Phase II deliverable.

PHASE III: Fully robust, ergonomic, cost-effective, manufactured commercialized product. Manufacturing capabilities and scale up plans shall be provided. Test results on robustness, shipping, electrical safety testing, accuracy, consistency, and comparability to current existing methodologies are required. Detailed product cost and consumable cost information is necessary. Specifications of manufactured product as well as manufacturing process need to be prepared and finalized. Materials, material properties, conditions under which product may be shipped and stored are needed.

REFERENCES:

1. Berry M., Malone E., Lipson H., (2005) “Freeform Fabrication of Zinc-Air Batteries with Tailored Geometry and Performance”, Proceedings of the 16th Solid Freeform Fabrication Symposium, Austin TX, Aug 2005, pp.295-307.

2. Blackhart C, Staab T, Cohen D, Feller S. “Automation of forensics sample collection using real-time 3-D laser tracking and playback system.”Proceedings of LabAutomation 2007; 2007 Jan 28–31; Palm Springs, CA. p. 118.

3. Cohen D.L., Malone E., Lipson H., Bonassar L.J, (2004) “Multi-Tissue Direct Freeform Fabrication of Spatially Heterogeneous Biological Implants”, Proceedings of the 15th Solid Freeform Fabrication Symposium, Austin TX, Aug 2004, pp.720-731.

4. Cohen D. L., Malone E., Lipson H., Bonassar L., (2006) "3D direct printing of heterogeneous tissue implants", Tissue Engineering, Vol. 12, No. 5: 1325-1335

5. Cohen D.L., Lipton, J., Cutler, M., Coulter, D., Vesco, A., Lipson, H. (2009) “Hydrocolloid Printing: A Novel Platform for Customized Food Production” Solid Freeform Fabrication Symposium (SFF’09), Aug 3-5 2009, Austin, TX, USA.

6. Cohen DL, Lo WM, Tsavaris AM, Bonassar LJ, Lipson H. “Improved quality of 3D-printed tissue engineering constructs through enhanced mixing.” Transactions of the 55th Annual Meeting of the Orthopaedic Research Society; 2009 Feb 22–25; Las Vegas, NV.

7. Cohen DL, Lo WM, Tsavaris AM, Bonassar LJ, Lipson H. “Improved quality of 3D-printed tissue constructs through enhanced mixing of alginate hydrogels.” Proceedings of the TERMIS-North American 2008 Annual Conference & Exposition; 2008 Dec 7–10; San Diego, CA.

8. Ballyns J, Cohen DL, Malone E, Lipson H, Bonassar LJ. “Evaluation of geometric fidelity for anatomically shaped tissue engineered constructs.” Proceedings of the 2008 BMES Annual Fall Meeting; 2008 Oct 2–4; St. Louis, MO.

9. Cohen DL, Tsavaris AM, Lo WM, Bonassar LJ, Lipson H. “Improved quality of 3D-printed tissue constructs through enhanced mixing of alginate hydrogels.” Proceedings of the Nineteenth Solid Freeform Fabrication Symposium; 2008 Aug 4–6; Austin, TX.

10. Cohen DL, Ballyns J, Malone E, Potter H, Maher SA, Wright TM, Lipson H, Bonassar LJ. “Geometric fidelity of SFF-based methods for tissue engineering of anatomically shaped constructs.” Proceedings of the 2006 BMES Annual Fall Meeting; 2006 Oct 11–14; Chicago, IL. d. 1600.

11. Cohen DL, Malone E, Bonassar LJ, Lipson H. “Direct freeform fabrication technique for bio-manufacturing of pre-seeded, spatially heterogeneous, anatomically-shaped alginate hydrogel implants.” Proceedings of the 2005 International Mechanical Engineering Congress and Exposition; 2005 Nov 5–11; Orlando, FL. d. 81067.

12. Cohen DL, Lipson H, Bonassar LJ. “Freeform fabrication of living tissue constructs using alginate hydrogel.” Proceedings of the 2005 BMES Annual Fall Meeting; 2005 Sep 28–Oct 1; Baltimore, MD. d. 1267.

13. Cohen DL, Maher S, Rawlinson J, Lipson H, Bonassar LJ. “Direct freeform fabrication of living cell-seeded alginate hydrogel implants in anatomic shapes.” Transactions of the 51st Annual Meeting of the Orthopaedic Research Society; 2005 Feb 20–23; Washington, DC. d. 1781.

14. Cohen D, Bonassar LJ, Lipson H. “3-D printing of spatially heterogeneous pre-seeded living-cell implants using alginate hydrogel.” Proceedings of the 2004 BMES Annual Fall Meeting; 2004 Oct 13–16; Philadelphia, PA. d. 966.

15. Cohen DL, Malone E, Lipson H, Bonassar LJ. “Direct freeform fabrication of spatially heterogeneous living cell-impregnated implants.” Proceedings of the Fifteenth Solid Freeform Fabrication Symposium; 2004 Aug 2–4; Austin, TX. p. 720–31.

16. Cornell Creative Machines Lab: Printing Food. Accessed at http://creativemachines.cornell.edu/node/194 on December 3, 2011.

17. Havener R., Boyea J., Malone E., Bernards D., DeFranco J., Malliaras G., Lipson H., (2007) “Freeform Fabrication of Organic Electrochemical Transistors”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007.

18. Hiller, J., Lipson, H., (2009) "Design and analysis of digital materials for physical 3D voxel printing", Rapid Prototyping Journal, Vol. 15, No. 2, pp. 137-149.

19. Hiller, J., Lipson, H. (2009) "Fully Recyclable Multi-Material Printing" Solid Freeform Fabrication Symposium (SFF'09), Aug 3-5 2009, Austin, TX, USA.

20. Hiller J., Lipson H., (2008) “Tunable Digital Material Properties for 3D Voxel Printers”, Proceedings of the 19th Solid Freeform Fabrication Symposium, Austin TX, Aug 2008.

21. Hiller J., Lipson H., (2007) “Methods of Parallel Voxel Manipulation for 3D Digital Printing”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007, pp. 200-211.

22. Lipton, J.I., Arnold, D., Nigl, F., Lopez, N., Cohen, D.L., Noren, Nils., Lipson,H., (2010) "Multi-Material Food Printing with Complex Internal Structure Suitable for Conventional Post-Processing", 21st Solid Freeform Fabrication Symposium (SFF'10), Austin Tx, USA.

23. Periard D., Schaal N., Schaal M., Malone E., Lipson H., (2007) “Printing Food”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007, pp.564-574.

24. Periard D., Malone E., Lipson H., (2007) “Printing Embedded Circuits”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007.

25. Periard D., Malone E., Lipson H., (2007) “Printing Food”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007.

26. Malone E., Lipson H., (2007) “The Factory in your Kitchen”, Proceedings of Mass Customization and Personalization (MCPC) 2007, Cambridge, MA, October 2007.

27. Malone E., Lipson H., (2007) “Freeform Fabrication of a Complete Electromechanical Relay”, Proceedings of the 18th Solid Freeform Fabrication Symposium, Austin TX, Aug 2007.

28. Malone E., Lipson H., (2006) “Freeform Fabrication of Complete Devices: Compact Manufacturing for Human and Robotic Exploration”, AIAA Space 2006, San Jose, CA, 19-21 Sept 2006, AIAA 2006-7406.

29. Malone E. (2006) “Faxing Artifacts: The promise of three-dimensional scanning and rapid prototyping of archaeological materials”, International Council of Archaeo-Zoologists - ICAZ 2006, Mexico City, Mexico, 23-28 Aug 2006, poster.

30. Malone E., Lipson H., (2006) “Fab@Home: The Personal Desktop Fabricator Kit”, Proceedings of the 17th Solid Freeform Fabrication Symposium, Austin TX, Aug 2006.

31. Malone E., Lipson H., (2005) “Freeform Fabrication of Ionomeric Polymer-Metal Composite Actuators”, Proceedings of the 16th Solid Freeform Fabrication Symposium, Austin TX, Aug 2005, pp. 484-502

32. Malone, E. and Lipson, H., 2004, “Solid Freeform Fabrication for Autonomous Manufacturing of Complete Robots”, Proceedings of Robosphere 2004, November 2004, NASA Ames Research Center, CA USA.

33. Malone E., Purwin, O., Lipson H., (2004) “Application of Machine Learning Methods to the Open-Loop Control of a Freeform Fabrication System”, Proceedings of the 15th Solid Freeform Fabrication Symposium, Austin TX, Aug 2004, pp.377-388.

34. Malone E., Lipson H., (2004) “Freeform Fabrication of Electroactive Polymer Actuators and Electromechanical Devices”, Proceedings of the 15th Solid Freeform Fabrication Symposium, Austin TX, Aug 2004, pp.697-708.

35. Evan Malone and Hod Lipson, (2004) “Functional Freeform Fabrication for Physical Artificial Life”, Ninth Int. Conference on Artificial Life (ALIFE IX), Proceedings of the Ninth Int. Conference on Artificial Life (ALIFE IX), pp.100-105.

36. Malone E., Rasa K., Cohen D. L., Isaacson T., Lashley H., Lipson H., (2003) “Freeform fabrication of 3D zinc-air batteries and functional electro-mechanical assemblies”, Proceedings of the 14th Solid Freeform Fabrication Symposium, Austin TX, Aug 2003, pp.363-374.

37. E. Malone, H. Lipson, 2002, “Solid Free-Form Fabrication For Self-Sustained Robot Ecologies”, Proceedings of Robosphere 2002, pp. 93-98, NASA Ames Research Center, CA USA.

KEYWORDS: 3D Printing, Fabrication, Medical Simulation, Synthetic Human Tissue Analogue, Medical Training, Simulated Tissue, Animal Tissue Replacement, Human Cadaver Replacement

DHP12-004 TITLE: Prototype, Open-Source, Universal Healthcare Exchange Language

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Prototype architecture to execute an open source, universal health exchange language, as described in a recent President’s Council of Advisors on Science and Technology (PCAST) Report.

DESCRIPTION: Most DOD, VHA, and civilian healthcare systems encounter significant challenges in exchanging health information due to the lack of a universal health exchange language. Without effective health information exchange, continuity of patient care is less than optimal, healthcare access and availability are hampered, and healthcare costs increase. This topic is of particular importance to DOD, which is a provider and payer of care for 9.6M beneficiaries. Two thirds of military healthcare is delivered in the civilian sector.

As a matter of background, the PCAST Report On “Realizing The Full Potential Of Health Information Technology To Improve Healthcare For Americans: The Path Forward”, sets forth general recommendations regarding how healthcare information technology can be used to improve healthcare access, availability, acceptability, continuity, cost-effectiveness, and quality. The report cites the beneficial work of the HHS Office of the National Coordinator (ONC) for Healthcare Information Technology in developing standards and an initial nationwide healthcare information exchange to share data to improve healthcare delivery and support research for the public good. The report points out that “national decisions can and should be made soon to establish a “universal exchange language” that enables health IT data to be shared across institutions; and also to create the infrastructure that allows physicians and patients to assemble a patient’s data across institutional boundaries, subject to strong, persistent, privacy safeguards and consistent with applicable patient privacy preferences.”

The PCAST report further states that, “creating the required capabilities is technically feasible, as demonstrated by technology frameworks with demonstrated success in other sectors of the economy. The best way to manage and store data for advanced health informatics is to break data down into the smallest individual pieces that make sense to exchange or aggregate. These individual pieces are called ‘tagged data elements, because each unit of data is

accompanied by a mandatory "meta-data tag" that describes the attributes, provenance, and required security protections of the data."

Current state: Some research surrounding use of healthcare metadata is underway and moving from academic labs into some early practical uses, such as demonstrated by Dr. Parsa Mirhaji for use in public health surveillance. Much of this research has been conducted using semantic web technologies employing the Resource Descriptive Framework (RDF), and Web Ontology Language (OWL), and query technologies such as SPARQL, which utilize the concept of "tuples", (subject, predicate, object), to relate data and achieve semantic interoperability. Other similar technologies exist, such as those from Metadata, Inc., although the semi-proprietary Metadata language, parts of which is available from Open Health Tools, is based on quintuplets vice tuples. Through their Health Data Dictionary (HDD) product, 3M has also supported some degree of semantic interoperability, using a knowledge representation scheme linked to a unique concept identifier, but it is not a true first-order predicate logic ontology. Language and Computing, now owned by Nuance, developed LinkBase, the world's largest medical ontology, with limited commercial success.

Adoption of these commercial technologies may have been limited by their proprietary, versus open nature, and associated licensing costs. It may be possible for some of these commercial technologies to be made open source, with companies then selling services around their technology, but this is a business decision that is up to the companies. Moving towards developing open source terminology mediation services may place these companies in a position wherein the Office of the National Coordinator for Healthcare IT could adopt those terminology mediation services for use in the Nationwide Health Information Network (NwHIN), and NwHIN Connect and Direct products (typically using a Berkeley Software Development License). In any event, the environment is ripe for continued academic and commercial collaboration under an STTR to advance the domain.

Desired State: Research conducted under this topic will directly support the PCAST and ONC visions, but would be conducted primarily on behalf of the Military Health System, which provides an integrated healthcare delivery system for 9.6 million beneficiaries. This care is delivered through a combination of direct care Military Treatment Facilities and private healthcare delivery organizations under the TRICARE triple option health benefits program. Nearly two thirds of healthcare is delivered to military beneficiaries through the private sector. Given that military families are also highly mobile, moving on average every three years to new duty stations, finding a way to exchange data and create a longitudinal virtual electronic health record is an important objective of military medicine. Clearly the research would also be extensible to other national publically and privately funded healthcare delivery systems and information exchanges.

The prototype to develop a universal exchange language for healthcare information and a digital infrastructure for locating patient records while strictly ensuring patient privacy may employ the U.S. Army Telemedicine and Advanced Technology Research Center's (TATRC) Early Stage Platform (ESP) for Research and Development, which provides a fully replicate DOD Electronic Health Record and CHCS computerized physician order entry and results retrieval system for third party development, using virtual machine access.

TATRC will coordinate this research closely with HHS, Office of the Nationwide Healthcare Information Coordinator, the Veterans Administration, and with the Center for Medicare Services (CMS). It is fully expected that the research will be extendable into the public good and will benefit the development of new electronic health records developed by the private sector that would utilize the universal exchange language.

PHASE I: In Phase I, the awardee will outline a strategic, operational, and technical alternatives to creating a prototype, open source, universal health exchange language service that can operate as a service on the NwHIN, and support health exchange for military medicine. Phase I work should center on a limited number of use cases to be determined in conjunction with the government Contracting Officer Representative. Phase I will also provide opportunity for consultation with ONC for Healthcare IT and other subject matter experts. At the conclusion of Phase I, the awardee will recommend a technical reference implementation architecture, which will then be built as a prototype in Phase II of the SBIR.

PHASE II: In Phase II, the awardee will build the universal health language prototype, as an open source service on the NwHIN Connect solution, and demonstrate the exchange of military, VA, and civilian health data with semantic interoperability in a laboratory setting, potentially using the TATRC early stage platform for research and

development. At the conclusion of Phase II, the prototype will be demonstrated to U.S. Army TATRC, Military Health System, HHS ONC for Healthcare IT, HHS CMS, Veterans Administration, and other government officials.

PHASE III: In Phase III, the universal health language service would be implemented on the NwHIN, or otherwise in local or regional health information exchanges to support scalable terminology mediation between electronic health records systems. Such work may also be commercialized and of interest to commercial electronic healthcare vendors. Ideally, the universal health language service would be an open source service, with the vendor choosing to sell services around the open technology.

REFERENCES:
1. President's Council of Advisors on Science and Technology (PCAST) Report On "Realizing The Full Potential of Health Information Technology To Improve Healthcare for Americans: The Path Forward, " December 2010, http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf

2. Marco Eichelberg, Thomas Aden And J Org Riesmeier, et al, "A Survey and Analysis of Electronic Healthcare Record Standards", http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.107.5349&rep=rep1&type=pdf

3. Parsa Mirhaji, Dean Allemang, Robert Coyne, S. Ward Casscells: Improving the Public Health Information Network through Semantic Modeling. IEEE Intelligent Systems 22(3): 13-17 (2007), http://www.computer.org/portal/web/csdl/doi/10.1109/MIS.2007.53

4. Parsa Mirhaji, Min Zhu, Mattew Vagnoni, Elmer V. Bernstam, Jiajie Zhang, Jack W. Smith: Ontology driven integration platform for clinical and translational research. BMC Bioinformatics 10(S-2): (2009) http://www.biomedcentral.com/1471-2105/10/S2/S2

5. Marco Eichelberg, Thomas Aden And J Org Riesmeier, et al, "A Survey and Analysis of Electronic Healthcare Record Standards", http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.107.5349&rep=rep1&type=pdf

6. Semantic Web Health Care and Life Sciences (HCLS) Interest Group http://www.w3.org/2001/sw/hcls/

7. W3C Semantic Web in Health Care and Life Sciences Tutorial, http://videolectures.net/iswc08_prudhommeaux_swhcls/

KEYWORDS: PCAST Report, Healthcare Information Technology, Universal Health Exchange Language, Patient Record Locator, Patient Privacy

DHP12-005 TITLE: Prototype Application of Mobile, Cloud-based, Watson-Like Technologies for TBI/PTSD Clinical Decision Support and Predictive Analytics

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Explore the use of natural language and clinical language understanding technologies, combined with IBM Watson-like technologies, to predict provisional diagnosis, provide clinical decision support, predictive analytics, and improved outcomes for mild TBI and PTSD patients. Develop a mobile, cloud-based architecture that can integrate with existing or improved clinical workflow, and ties to the Electronic Health Record.

DESCRIPTION: For more than 30 years, academic researchers have studied the use of computers to predict diagnoses and make recommendations for treatment. Such work has developed a number of standards and frameworks for developing and executing clinical decision support guidelines and algorithms, such as SAGE, EON, GLIF, and ATHENA. Several commercial products to couple knowledge with problems, and to predict diagnosis and recommend treatments, such as PKC Couplers, Agile Diagnosis, Isabel, TheraDoc, Zynx, and others, and have emerged on the marketplace but have not been widely adopted, perhaps because the clinical decision support

guidelines are typically segregated to one disease domain, and do not cross domains. In addition, such clinical decision support systems have not been truly integrated into a clinician's workflow and/or into the Electronic Health Record. Maintaining current medical knowledge within the algorithms has also posed considerable challenge. The TATRC Morningside Initiative, started in 2007, was an attempt at a private-public partnership to create an open source repository of clinical knowledge.

Two recent developments may change adoption rates, however. First, Qualcomm has joined forces with X-Prize foundation to over a $10M prize to any individual or company that can develop a mobile computerized decision support tool that can diagnosis patients as good as a panel of board certified physicians. Second, using technology that has evolved out of the widely advertised Watson Jeopardy game challenge, IBM has announced a major collaboration with WellPoint to use Watson technologies to diagnosis and recommend treatments for oncology patients. Several key partnerships have formed between Nuance, IBM, and 3M to apply speech recognition, natural language processing, and medical ontologies towards development of improved clinical decision support tools to predict diagnoses and offer treatment options. A number of companies are also releasing products that use embedded sensors to collect patient physiological signs, and include them as input to the clinical decision support algorithms. Some of these products are smart-phoned based, although research in mobile, cloud-based technologies is just beginning and is 5 to 10 years from maturation.

PHASE I: In Phase I, the awardee will develop alternative strategic, operational, and technical architectural views for a clinical decision support aid which can predict diagnosis from patient history, symptoms, and/or physiological signs, with a focus on using mobile, cloud-based speech recognition, natural language processing, and IBM Watson-like technologies to capture and analyze data. Initial use case will focus on improving outcomes for mild TBI and PTSD patients. The awardees will work with TATRC and its partners to incorporate existing, ongoing natural language processing and clinical decision support work as applicable, and produce a complete design document for a clinical decision support tool that will predict diagnoses based on patient history and symptoms. The government encourages evaluating the use of cloud-based algorithms which can be executed on mobile devices. The government also encourages the use of standards based, open source clinical practice guidelines for execution. To the extent that the specific pathways can be seen within the algorithm, and are not proprietary, they can also be used to support training of residents.

PHASE II: In Phase II, one or more awardees from Phase I will build and test a prototype. TATRC can provide use of a virtualized Early Stage Development (ESP) platform that can be used in the project, although a vendor use fee will be negotiated under a CRADA. The ESP platform has access to a fully functional AHLTA and CHCS development and test environment. TATRC will also make available open source VISTA code that the awardees can consider using in the project. TATRC will attempt to supply sufficient military clinical subject matter expertise to test and evaluate the prototype as to clinical relevance, accuracy, and usability. The awardees should also provide their own clinical expertise in addition to what expertise the government may provide.

PHASE III: It is anticipated that this research will yield improvements in application of mobile-based natural language processing, clinical language understanding, text analytics, computerized algorithms, and artificial and business intelligence, that may have applicability outside of the medical domain and may be applied in other domains, such as military intelligence. The government also expects that this research may yield new developments in computerized modeling and simulation to train personnel in a number of industries.

REFERENCES:

1. http://psg-mac43.ucsf.edu/ticr/syllabus/courses/2/2003/03/04/lecture/readings/evaluating%20informatics%20apps.pdf

2. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2243943/pdf/procamiasymp00003-0335.pdf

3. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC116322/

4. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2243832/pdf/procamiasymp00003-0680.pdf

5. http://sage.wherever.org/model/approach.html

6. http://www.amia.org/sites/amia.org/files/Concept-Paper-11062007.pdf

7. http://latimesblogs.latimes.com/technology/2011/09/ibm-watson-wellpoint.html

8. http://tech.uchicago.edu/features/20111111_webapp/

9. http://www.isabelhealthcare.com/home/default

10. http://www.theradoc.com/

11. http://www.zynxhealth.com/Solutions.aspx

12. http://xnet.kp.org/permanentejournal/spr10/ProblemKnowledgeCouplers.pdf

13. http://en.wikipedia.org/wiki/Tricorder_X_PRIZE

KEYWORDS: Star-Trek Medical Tri-Corder, IBM Watson-Like Technologies, Clinical Language Understanding, Natural Language Processing, Speech Recognition, Predictive Diagnosis, Clinical Decision Support, Predictive Analytics, Improved Health Outcomes, Mobile Health, mHealth, Cloud Computing, EHRs, Usability, Computability

DHP12-006 TITLE: Cohort Builder for Healthcare Quality Assurance and Comparative Health Effectiveness Research

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Define and prototype architectural alternatives resulting in an easy-to use cohort builder for clinicians, nurses, and QA personnel. The cohort builder would be used for conducting quality assurance and comparative health effectiveness research; to recapitulate findings in the literature; and to remediate patient care issues for chronically ill patients.

DESCRIPTION: The mantra of the Military Health System is to deliver available, accessible, acceptable, high quality, continuous, and cost effective healthcare to 9.6M beneficiaries. Each budget cycle the Military Health System is called upon to deliver continuously improving healthcare, yet has ever-increasing constraints placed on its resources. In order to do more with the same or less level of resources, and without adversely impacting health outcomes and patient safety, the Military Health System should engage in comparative health research studies to ascertain which treatments provide the best outcomes at equal or less cost than other therapies. Additional studies should be conducted to determine why one clinician may get better outcomes at equal or less cost than his/her peers, considering case mix (i.e. clinician profiling). Yet the Military Health System does not currently have the clinical analytical tools to conduct such analyses. Although the Military Health System (MHS) has a number of Automated Information Systems (AIS) in its inventory, including AHLTA, Clinicomp Essentris, CHCS, ICDB, MDR, M2, CDM, HSDW, AFCHIPS, Air Force Population Health Portal, Medical Home Clinical Data Mart, and others, there is no system that allows clinicians to build cohorts for quality assurance studies or comparative health effectiveness research, and compare those cohorts as to differences in health outcomes.

In the current state, clinical quality assurance and comparative health effectiveness research studies cannot be easily conducted. Executing such studies requires extensive expertise in the form of data priests and statisticians, to identify appropriate data, pull it from the right sources, consolidate it, and analyze it. Conducting such studies can take months. Issues impacting the care of chronic care patients at the point of care cannot be easily identified or remediated at the point of care. Studies in the literature cannot be re-capitulated in a clinician's panel in a matter of minutes. Of additional concern is the current rapid promulgation of domain-specific data marts and registries in the new Centers of Excellence, with no robust toolsets to conduct health outcomes on those registries.

In the envisioned state, access to information would be democratized, with no need for data priests or statisticians. Clinicians, nurses, and QA personnel would access an easy-to-use cohort builder on their desks, that allows one to quickly build cohorts on any combination of parameters collected in base transaction systems; which supports different time events for different parameters; and provides for risk windows and blackout periods; for the primary purpose of remediating issues identified in chronic care patients. In addition, the cohort builder would be self-documenting in terms of identifying the basis for the cohorts, and produce analysis suitable for publication in research journals. The tool would incorporate a statistical service to make automated, on –the-fly comparisons between cohorts as to differences in morbidity and mortality. All parameter lists, cohorts, and outcomes could be saved as objects and reused. The output of one study could become the input for another study.

PHASE I: In Phase I, awardees will outline strategic, operational, and technical architecture alternatives for a prototype cohort builder to support health outcomes studies. The alternatives would include an analysis of existing GOTS and COTS products and their ability to be integrated into current clinical intelligence frameworks. The output of Phase I is a report that would provide details on the cohort builder would integrate with existing and planned MHS transactional, data marts, registries, and data warehouses, and which would serve as a complete design document to actually build a prototype cohort builder.

PHASE II: In Phase II, the SBIR recipient(s) will build or buy a cohort builder, integrate it with various MHS data sources, and pilot the tool with approximately 20 clinicians at the Walter Reed Army Medical Center, USU, and Centers of Excellence. During the prototype, the Phase II recipient(s) would collect data on the usability of the cohort builder in conducting health outcomes studies, and conduct measurements on how the cohort builder improves the effectiveness and efficiency of outcomes studies over previously conducted manual efforts. Any particular studies conducted would require IRB approval in advance.

PHASE III: Clinical intelligence and/or electronic health record vendors that support the analysis of healthcare delivery in traditional inpatient and outpatient settings could commercialize this research for use in new markets, including the life sciences. Those conducting comparative effectiveness of commercial products might even adopt the work outside the healthcare of life sciences arena.

REFERENCES:

1. http://www.ahrq.gov/clinic/outfact.htm

2. http://www.hhs.gov/recovery/programs/os/cerbios.html

3. http://www.hhs.gov/recovery/programs/cer/index.html

4. http://www.health.mil/MHSCIO/programs_products/DHSS/DHSS-Products/CUD.aspx

5. http://dhims.health.mil/products/garrison/index.aspx

6. http://exploreclg.montefiore.org/

7. http://www.microsoft.com/en-us/microsofthealth/products/microsoft-amalga.aspx

8. http://www.inforsense.com/industries/healthcare/index.html

9. http://www.sap.com/solutions/sapbusinessobjects/large/business-intelligence/index.epx

KEYWORDS: Cohort Builder, Quality Assurance Studies, Health Outcomes Studies, Comparative Effectiveness Research, Clinical Analytics, Advanced Clinical Research System (ACRIS), Clinical Intelligence, Business Intelligence

DHP12-007 TITLE: Novel Sampling Device for the Surveillance of Adult Flying Insect Vectors

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop a novel freestanding, lightweight, compact, portable sampling device to collect a broad spectrum of adult flying insect disease vectors.

DESCRIPTION: Vector borne disease historically ranks among the leading causes of Disease and Injury (D&I) among U.S. service members deployed in support of military operations. Entomologists perform vector surveillance in order to mitigate the threat of vector borne disease among military populations. Vector surveillance provides information on density, abundance, distribution, and species composition of vectors as well as a way to evaluate results of control measures. In order to properly characterize the threat of vector borne diseases and develop effective control techniques, equipment used in vector surveillance operations needs to be highly effective, easily transported, and relatively maintenance free. Vector surveillance devices should ideally be able to target multiple groups of insect vectors and be self-contained, to eliminate the need for numerous devices and reliance on external power or fuel sources.

The CDC light trap was developed in the mid-20th century and has been virtually unchanged since the 1960s. It is the primary piece of equipment used in vector surveillance for adult insect vectors, such as mosquitoes and sand flies, in military and civilian vector surveillance and control programs. Depending on availability, the CDC light trap is sometimes augmented with carbon dioxide from dry ice or another source. Unfortunately, even with carbon dioxide supplementation, this trap does not work well for many militarily important adult insect vectors, including the vectors of Dengue fever, malaria, and leishmaniasis.

While the CDC light trap is recognized to have serious flaws in its ability to provide reliable, accurate vector surveillance for most adult flying insect vectors, it remains the standard trap used by military entomologists during deployments. As a component of the U.S. Army Medical Equipment Set (MES) Entomological Kit Field (UA 124A), it is fielded to all level II and III Army preventive medicine assets for operational use worldwide. Unfortunately, this trap has not kept up with the rapidly changing understanding of insect behavior and improving technology in recent years.

Over the last two decades, newer adult flying insect traps have been developed in the commercial sector in an attempt to provide more effective means of surveying for important insect vectors. These newer devices rely on chemical cues, such as carbon dioxide or other chemicals that are present in human skin secretions, and/or different wavelengths of light. While some of these new traps, including the Mosquito Magnet, BG Sentinel, and Zumba traps, are more effective than the CDC light trap at collecting certain groups of host seeking mosquitoes, none of these traps are broadly effective against the variety of flying adult insect vectors (Bhalala and Arias 2009, Dusfour et al 2010). In addition, many of the new traps available are not as portable as the CDC light trap and still require reliance on external power or fuel sources, ranging from large batteries to propane tanks.

The DoD Armed Forces Pest Management Board (AFPMB) has identified the need for new or improved vector surveillance systems as the most important research priority for military entomology (AFPMB 2011). Military vector surveillance varies from other governmental and non-governmental vector surveillance efforts in that military entomologists need the tools to conduct accurate surveillance in any environment or geographic region to which they may be deployed. Furthermore, military entomologists need tools that are easily transported in order to ensure that they can get them to any location, no matter how remote, where vector surveillance will be required. A vector surveillance tool that is broadly effective, reliable, and portable will fill a major gap in our ability to accurately characterize the threat of vector borne disease in military operations.

The purpose of this project is to develop a novel device to perform surveillance on adult insect disease vectors. This device should be attractive to a variety of vector groups, including mosquitoes (Anopheles, Aedes, and Culex species) and sand flies (Phlebotomus and Lutzomyia species). Efficacy against black flies, biting midges, and tsetse flies would be desirable, but is not the primary focus of this effort. The trap should be freestanding, lightweight, compact, portable, and should not require an external power source. The internal power source should be DoD Green Energy compliant. The device may be either one standard piece of equipment that is effective against the

broad range of vectors outlined above or it may consist of a modular design that can be tailored to the specific group of interest.

PHASE I: This phase of the SBIR should focus on developing the initial concept and design for the surveillance trap.

PHASE II: During the Phase II portion of this SBIR, the awardee should develop the prototype trap design. Once the initial prototype is developed, it should be tested in both laboratory and field environments for efficacy in collecting a variety of insect disease vectors, such as mosquito and sand fly vectors. Field testing should include operation in a variety of environments, including desert and tropical environments. At the conclusion of Phase II, the awardee should have developed a prototype that is effective in sampling for mosquitoes (Anopheles, Aedes, and Culex species) and sand flies (Phlebotomus and Lutzomyia species), is freestanding, lightweight, compact, portable, and operates without an external power source.

PHASE III: The proposed SBIR has commercial applications outside of the military. This sort of novel vector collection device could be used in public health disease surveillance programs (both governmental and non-governmental) and by public health researchers. At the completion of a successful Phase II, the company should seek funding from either a private company for commercialization of the product or through advanced development funding. The product resulting from this SBIR should be considered for NSN assignment so that it may be readily purchased by military and other US governmental organizations. In addition, the product should be considered for inclusion in the MES Entomological Kit Field as a replacement for the CDC light trap. The product should also be commercially available for other vector borne disease surveillance applications.

REFERENCES:
1. Armed Forces Pest Management Board. 2011. Department of Defense Research Requirements for Pest Management for FYs 2011-2012, signed 24 May 2011.

2. Bhalala, H and JR Arias. 2009. The Zumba mosquito trap and BG-Sentinel trap: novel surveillance tools for host-seeking mosquitoes. Journal of the American Mosquito Control Association 25(2): 134-139.

3. Braks, M, J van der Giessen, M Kretzschmar, W van Pelt, EJ Scholte, C Reusken, H Zeller, W van Bortel, H Sprong. 2011. Towards an integrated approach in surveillance of vector-borne diseases in Europe. Parasites and Vectors 4: 192.

4. Dusfour, I, R Carinci, P Gaborit, J Issaly, and R Girod. 2010. Evaluation of four methods for collecting malaria vectors in French Guiana. Journal of Economic Entomology 103(3): 973-976.

5. Owino, EA. 2011. Sampling of An. gambiae ss. mosquitoes using Limburger cheese, heat and moisture as baits in a homemade trap. BMC Research Notes. 4: 284.

KEYWORDS: entomology, vector borne disease, surveillance, trap, mosquito, sand fly

DHP12-008 TITLE: Multisegmental Sensor Integration for Balance Control

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop and optimize integration of networked sensors located on torso and appendages of body to assess accurate center of-gravity and center-of-pressure in real time.

DESCRIPTION: The most frequent and challenging symptom experienced by military personnel exposed to IED or concussive events is dizziness or loss of balance (Balaban 2009). Balance is also an issue for warfighters who require prostheses to compensate for loss of limbs. Biofeedback vibrotactile prostheses have recently been

developed to assist patients during recovery while they are undergoing rehabilitation to achieve unsupported upright posture. (Atkins 2011, Rupert 2010). These sensory aids receive center-of-pressure (COP) and derived center-of-gravity (COG) information from static force plates. In order to provide assistive sensory information during the dynamic condition of walking without falling, it is necessary to provide real time COP/COG information to the assistive device.

Recent advances in Micro-Electrical-Mechanical Systems (MEMS) have made accessible a variety of extremely small, rugged, reliable, low power consumption, and inexpensive sensors of acceleration and pressure. A collection of these devices should be capable of providing similar proprioceptive information that the distributed biological sensors of the human body provide the brain to carry out complex mobility tasks. What are the minimal number, location and type of sensors required to provide real-time balance information to an integrative device, which with an appropriate algorithm can provide assistive cueing to prevent falls?

The technology achievements in MEMS, garments with built in electronics, and miniaturized short-range wireless transmission now create the opportunity to efficiently link multiple sensors (e.g. inertial, pressure, etc) that can provide the basis for "real-time" COG/COP information, which can be integrated with additional sensors and utilized to provide the patient tactile, visual and auditory cueing systems to enhance balance during dynamic conditions. This same technology has immediate and obvious applications to robotics.

This topic seeks proposals addressing both hardware and software issues: the hardware must provide sufficient information to provide real-time COG/COP no matter how the extremities are being moved dynamically in space and the software should be able to predict falls during dynamic walking conditions.

PHASE I:
1) Develop and demonstrate a prototype integration of distributed sensors capable of providing real-time COG and COP for ambulatory human or robot.

2) Outline plan for software development capable of predicting excursions outside the normal envelope of walking.

PHASE II:
1) Building on the prototype from Phase I, test and demonstrate the system hardware and the software algorithm developed to predict falls.

PHASE III:
1) Provide caretakers of wounded warriors with ambulatory device to replace current static force plate training and evaluation devices.

2) Incorporate balance technology into humanoid robotics.

REFERENCES:
1) http://www.dcoe.health.mil/Content/Navigation/Documents/Balaban.pdf

2) Atkins, KL, 2010. Vibrotactile Postural Control in Patients that have Sit-to-Stand Balance Deficit and Fall. U.S. Army Aeromedcial Research Laboratory. Retrieve from http://www.usaarl.army.mil/TechReports/2010-18.pdf

3) Rupert AH, Lawson BD. 2011, Initial Consideration of the Feasibility and Optimal Application of Tactile Sway Cueing to Improve Balance among Persons Suffering from Disequilibrium. U.S. Army Aeromedical Research Laboratory. Retrieve from http://www.usaarl.army.mil/TechReports/2011-01.pdf

KEYWORDS: Balance, Mild Traumatic Brain Injury, prosthesis, falls, proprioceptive, tactile, biofeedback, rehabilitation.

DHP12-009 TITLE: Ear Protection Validation System

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop a user-friendly, portable, universal hearing protection device (HPD) field attenuation estimation system (FAES) that deployed or garrison personnel can use to measure the effective noise protection provided by a hearing protection device or system that is fit and worn in the field.

DESCRIPTION: It is generally understood that hearing protection devices typically fail to provide the protection that is measured in carefully controlled laboratory tests conducted in accordance with national testing standards (e.g., ANSI/ASA 12.6-2008). Berger (1993) conducted a meta-analysis of a number of field noise attenuation measurements and concluded (1) that the noise protection (as defined by the protectors' Noise Reduction Ratings [NRRs]) as seen in the field (i.e., real world) are appreciably lower than the NRRs calculated from carefully controlled standard-based laboratory studies and (2) that there is no clear relationship between the laboratory measurements and the real-world performance of the various hearing protectors. These two observations are valid for both insert (i.e., earplug) devices and circumaural (i.e., ear muff) devices.

Berger (1980) summarizes various reasons why the field measurements do not meet the numbers obtained in the laboratory (comfort, utilization, fit, compatibility, readjustment, deterioration, and abuse). The point is, however, that only highly trained and motivated users of hearing protection devices can obtain consistent fits yielding noise protection that approaches that measured in the laboratory.

Furthermore, hearing protection devices are not being employed sufficiently or properly in the military. Bjorn, Albery, Shilling and McKinley (2005) conducted a survey of hearing protector use by flight deck crews on six US Navy capital ships, four aircraft carriers and two amphibious ships. (Three ships were surveyed from the Second [Atlantic] and Third [Pacific] fleets.) They reported that only 53% of the flight deck crew that were surveyed (and who were required to wear double protection [i.e., earplugs and earmuffs]) wore earplugs and only 7% wore their earplugs in a manner to achieve the published 22 dB noise protection. Thus, the 46% of the Sailors that actually used earplugs wore them incorrectly.

PHASE I: This topic seeks the development of a hearing protection validation system for use by medical or trained deployed personnel to evaluate the fit and protection of hearing protection devices. It will provide a single value Personal Attenuation Rating (PAR), calculate protected exposure levels in dBA, calculate protected exposure time limits, provide a percent dose estimate, conduct testing using a Field Microphone-In-Real-Ear (F-MIRE) technique that does not modify the hearing protection device, be capable of testing attenuation of any commercially available device including single, double, and triple (Active Noise Reduction) hearing protective devices, complete all measurements bilaterally in 15 minutes or less, be sold at a fixed single unit price ($2500 - $3500 range to include computer re: (2011 prices), use an iPad®, tablet or portable hardware and operating system technology, have little to no consumables, have up-gradable software, be portable (less than 15 lbs), be ruggedized and durable for field or deployed use, be capable of data import and export from and to existing DoD systems, have computer interface capability, have database extraction and Excel file data transfer modality, be capable of testing multiple individuals concurrently (up to 8-10), be capable of DoD service or unit-self calibration, have a color screen display, produce a printable report, have an examiner testing menu, have a patient instructional display screen, provide individualized patient results and instructional materials, and be compliant with all current applicable ANSI standards.

The Phase I deliverable will include an initial design concept that addresses solutions for at least 80% of the HPD FAES characteristics described in the previous paragraph.

PHASE II: During Phase II, the awardee will implement the best approaches from Phase I into hardware and software and develop, test, and demonstrate all of the requirements of the HPD FAES noted above. At the end of Phase II, the company will deliver to the US Army Aeromedical Research Laboratory three (3) field-ready prototypes for laboratory and field testing. Laboratory testing will include, but not be limited to, comparisons with hearing protection performance measurement systems such as those that adhere to the requirements specified by ANSI/ASA S12.6 "American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors" (2008). Field testing will involve insertion of the device into an Army hearing conservation clinic and its use included as part of the Army Hearing Program (2008).

PHASE III: The problem of HPD fit and fit verification is one faced by military, civilian governmental organizations (e.g., law enforcement agencies), and industry. The FAES developed as a result of this SBIR will be a valuable tool for all environments (including recreational environments) in which noise hazards exist and hearing protection is mandated or recommended. The Occupational Safety and Health Administration's (OSHA) Alliance Program (2008) notes that individual HDP fit verification testing is an emerging "best practice" trend in hearing conservation programs. Phase III deliverables will be a validated, ruggedized FAES that is easily and reliably manufactured and can be utilized in harsh environments including military forward operating bases, shipboard, and on factory floors.

REFERENCES:

1. Alliance., N. O. (2008). Best Practice Bulletin: Hearing Protection-Emerging Trends: Individual Fit Testing. Retrieved 26 September 2011, from http://nhca.affiniscape.com/associations/10915/files/AllianceRecommendationForFitTesting_Final.pdf

2. AMEDDC&S. (2008). Special Text 4-02.501: Army Hearing Program. Retrieved from http://militaryaudiology.org/site/wp-content/images/st_4_02_501.pdf.

3. ANSI/ASA. (2008). S12-6-2008 American National Standard Methods for Measuring the Real-Ear Attenuation of Hearing Protectors. Melville, NY: Acoustical Society of America.

4. Berger, E. H. (1980). EARLog #5 - Hearing Protector Performance: How They Work - And - What Goes Wrong in the Real World. Sound and Vibration, 14(10), 14-17.

5. Berger, E. H. (1993). EARLog #20 - The Naked Truth About NRRs. Indianapolis, IN. Retrieved 26 Septemver 2011, from http://www.e-a-r.com/pdf/hearingcons/earlog20.pdf

6. Bjorn, V. S., Albery, C. B., Shilling, R., & McKinley, R. L. (2005). U.S. Navy Flight Deck Hearing Protection Use Trends: Survey Results. New Directions for Improving Audio Effectiveness (pp. 1-1 - 1-20). Neuilly-sur-Seine, France: RTO.

KEYWORDS: hearing protection, fit testing, field attenuation estimation

DHP12-010 TITLE: Self Powered Biosensors

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Self-powered wearable biosensors will be developed to provide continuous health monitoring, in particular respiratory effort, and ECG monitoring. It will be demonstrated that wearable biosensors can be self-powered by harvesting ambient energy or monitored physiological signals.

DESCRIPTION: Self-powered wearable biosensors could provide a powerful tool for continuous medical monitoring, and for monitoring personnel carrying heavy loads or in high-stress situations, such as monitoring Warfighters health, providing support for assessing Warfighter readiness and feedback mechanism for improving Warfighter performance, and reducing Warfighters' battery load. To enable wearable sensors, power on the order of mW must be available to enable continuous data sampling and processing, and wireless data transmission [1, 2]. Power that far exceeds those requirements, on the order of Watts, has been extracted from human gait using shoe, knee, and back-pack mounted generators [3-5]. Human energy sources may potentially provide not only a power source, but also physiological information [6-7]. In particular, respiratory effort and bioelectricity are always present energy sources that intrinsically carry rich physiological information. Respiratory effort available power has been estimated to be between in the mW range [3, 7]. Innovative solutions are being sought to provide and maintain continuous medical and health support for any operation requiring military service, through deployment of wearable

biosensors. Minimum accomplishments include monitoring of at least one respiratory parameter, such as respiratory rate, and at least one cardiac parameter, such as heart rate. It is required that sensor will derive electric energy from ambient sources or physiological signals. Ergonomic design embedded in clothing, continuous (24/7) operation, and wireless connectivity must be demonstrated. Use of a small, light, rechargeable battery is acceptable.

PHASE I: During Phase I, technical feasibility of the proposed approach will be determined. Energy source will be identified for powering wearable biosensors. Required Phase I deliverables will include initial biosensor concept design, energy harvesting and consumption rate analysis, and plan for ergonomic deployment of the proposed concept.

PHASE II: During Phase II, a commercially viable prototype will be fabricated and tested. Proposed self-powered, wearable biosensor concept will be validated, and component design, and system fabrication will be completed. The operation of the ergonomic prototype will be demonstrated. Required Phase II deliverables include wearable biosensor prototype, including ergonomic energy harvesting and physiological sensing hardware, robust software for physiological information extraction, and low-power wireless connectivity.

PHASE III: There are clear commercial opportunities for continuous medical monitoring. The major military application are monitoring Warfighters health in training and deployment, providing support for assessing Warfighter readiness and feedback mechanism for improving Warfighter performance, and reducing Warfighters' battery load. The major civilian application is remote monitoring of patients with chronic disease, and human performance monitoring during athletic training.

REFERENCES:
[1] W. Qin and W. Yang, "Energy Consumption Model for Power Management in Wireless Sensor Networks," 4th Annual IEEE Communications Society Conference on Sensor, Mesh and Ad Hoc Communications and Networks, 2007. SECON '07, pp. 142-151, San Diego, CA.

[2] TI Application Note, "CC430 combines the ultra-low-power MSP430™ Microcontroller with TI's Low-Power RF Technology," available at http://www.ti.com/lit/ml/slat124a/slat124a.pdf

[3] T. Starner and J. Paradiso, "Human Generated Power for Mobile Electronics," in Low Power Electronics Design, CRS Press, Fall 2004.

[4] J. Kymisis, C. Kendall, J. Paradiso, and N. Gershenfeld, "Parasitic Power Harvesting in Shoes," Second International Conference on Wearable Computing, 1998.

[5] L. C. Rome, L. Flynn, E. M. Goldman, and T.D. Yoo, "Generating electricity while walking with loads," Science, Vol. 309, Sept. 2005, Page(s): 1725-1728.

[6] B. Padasdao, and O. Boric-Lubecke, "Respiratory Rate Sensing Using Servo Motors," IEEE EMBC2011, Boston MA, August 2011.

[7] E. Shahhaidar, M. Wolfe, R. Ghorbani, and O. Boric-Lubecke, "Electromagnetic Generator as Respiratory Effort Energy Harvester," IEEE Power and Energy Conference, Urbana-Champaign, Illinois, February 2011.

KEYWORDS: biosensors, wearable, self powered, energy harvesting, respiratory rate, heart rate, continuous monitoring.

DHP12-011 TITLE: Antimicrobial Textiles

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: The objective of this research is to develop durable, scalable, robust and effective long-term antimicrobial textile finish.

DESCRIPTION: There is a continuing need for antimicrobial textiles to provide a range of capabilities to the DOD. These include improved hygiene for soldiers via integration into uniforms to control odor; in medical textiles to control the transmission of pathogenic bacteria in field medical shelters and military hospitals.

The goal of this topic is to identify light-weight, durable, antimicrobial finishes for textiles such that no degradation of other properties (e.g., porosity, mechanical properties) occurs. This is an important component in the overall strategy for improving soldier performance, and the development of Smart Textiles. Research will focus on developing and optimizing catalytic antimicrobial systems for direct integration into fabric for clothing, shelters, etc. The resulting technology should be easily integratable into fabric weaving and manufacture, and scalable to a high through-put process, allowing large volumes of fabrics to be treated.

PHASE I: Initial research will focus on chemical functionalities that can be applied as a fabric finish to provide high antimicrobial activity. Key functional properties that need to be addressed include non-leaching behavior of the coating, and an assessment of antimicrobial activity against Gram positive and Gram negative bacteria. Application of the finish must not lead to significant degradation of other properties (i.e., porosity, dyeability, printability, durability, mechanical strength, flexibility).

PHASE II: In this Phase, the process and characterization should be expanded to include cotton, polyester, and nylon and polyaramid textiles. Antimicrobial activity must be determined for coatings on all fiber types. Uniformity of the finish on each type should also be demonstrated. Textile properties should be determined using reliable metrology, and under typical conditions encountered by Soldiers and after multiple laundering cycles. The final coating and textile must be characterized to provide data on the extent of coating coverage, functional group density, coating adhesion, and antimicrobial activity and lifetime.

PHASE III: This technology will have both DoD and civilian applications, including antimicrobial textiles, anti-infective wound dressings, hospital textiles, bedding, wipes, HVAC filters, and medical devices.

REFERENCES:

1. Desai, R., P. S. Pannaraj, et al. (2011). "Survival and transmission of community-associated methicillin-resistant Staphylococcus aureus from fomites." Am J Infect Control 39(3): 219-225.

2. Keen, E. F., 3rd, C. K. Murray, et al. (2010). "Changes in the incidences of multidrug-resistant and extensively drug-resistant organisms isolated in a military medical center." Infect Control Hosp Epidemiol 31(7): 728-732.

3. Kramer, A., I. Schwebke, et al. (2006). "How long do nosocomial pathogens persist on inanimate surfaces? A systematic review." BMC Infect Dis 6: 130.

4. Maillard, J. Y. (2005). "Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems." Ther Clin Risk Manag 1(4): 307-320.

5. Miller, L. G. and B. A. Diep (2008). "Clinical practice: colonization, fomites, and virulence: rethinking the pathogenesis of community-associated methicillin-resistant Staphylococcus aureus infection." Clin Infect Dis 46(5): 752-760.

6. Neely, A. N. and M. P. Maley (2000). "The 1999 Lindberg award: 3% hydrogen peroxide for the Gram-positive disinfection of fabrics." Journal of Burn Care and Rehabilitation 20(6): 471-477.

7. Smith, T. C., E. D. Moritz, et al. (2010). "The environment as a factor in methicillin-resistant Staphylococcus aureus transmission." Rev Environ Health 25(2): 121-134.

8. Trillis, F., 3rd, E. C. Eckstein, et al. (2008). "Contamination of hospital curtains with healthcare-associated pathogens." Infect Control Hosp Epidemiol 29(11): 1074-1076.

KEYWORDS: Antimicrobial, Coatings, Polymers, Surfaces, textiles, infection

DHP12-012 TITLE: Biosensor and Controller for Closed Loop Anesthesia Delivery System

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop solution to enable closed loop anesthesia delivery system that can be used in far forward operations with regulatory plan for FDA approval, leading to commercialization of the product for use in the United States.

DESCRIPTION: Total intravenous anesthesia (TIVA) technique through a target controlled infusion (TCI) approach is an accepted method of inducing and maintaining sedation and analgesia in Europe and other parts of the world, except the United States. Advantages of TIVA include improved postoperative outcomes and faster recovery with minimal side effects such as postoperative nausea and vomiting. Use of TCI anesthesia (TCIA) in the United States and in theater of operations for the United States Armed Forces could improve treatment of casualties including service members, but it is currently not possible because there is no FDA approved TCI devices on the market. One of the reasons for this absence of FDA approved TCI devices stems from a safety concern due to the fact that TCIA infusion rates are determined by population-based pharmacokinetic data and individual patient biometrics. Therefore, the exact targeted plasma or effect-site concentration selected by the anesthesiologist is more art than science (i.e. lacks precision). Current TCI devices with biofeedback for closed loop control of propofol infusion exists, using bispectral impedance brain monitoring as the biofeedback for example to guide anesthesiologist the level of consciousness in the patient. Although such method has been validated in clinical studies and can be used in feedback control paradigms, there are limitations to bispectral impedance brain monitoring for closed-loop propofol delivery. Chief concerns include that the level of consciousness is an indirect measure of the level of drug in the blood and as such is a delayed biomarker and that bispectral impedance brain monitoring does not provide information regarding the potentially lethal levels of the drug (i.e. acute toxicity). Hence, inclusion of a biosensor would be one approach that could provide for direct measured drug levels in the serum and development of an algorithm to control infusion rate of drugs in TCI devices would enable automated TCIA with minimal additional external devices and monitors that add more weight and volume, which need to be minimized in the far forward operations.

The algorithm for correlating blood concentration to individual pharmacodynamics needs to be accurate and responsive (i.e. less than 1 second response time) to ensure the appropriate conscious state is reached without overdosing or under dosing the patient. The objective of this SBIR is to solicit for concepts that will enable automated TCIA system that could also be deployed for use in military theaters, to include far forward surgical teams and providers. Since existing TCI devices are already available, the solution should not include redesign of this component, but should focus on components that can be easily integrated into existing TCI devices to enable direct measurement of drug level and automation of the device, minimizing volume and weight for portability and taking into design considerations to fit within the environment. Due to the range of variance between individuals in the normal pharmacodynamics and kinetics of propofol, the functional physiologic end point is critical in assessing the patient's conscious state. Therefore, innovation is also solicited for other biomonitoring concepts (other than bispectral impedance brain monitoring) that assess physiological parameters to guide anesthesiologist the depth of anesthesia whether the concept is used as an addition, separate, or alternative feedback control to direct measure of analgesia, but must address weight, volume, and ease of use to enable operations in the far forward.

The proposed solution must account lags whether using physiologic state assessment and/or analytics associated with on-line propofol analysis, with less than 1 second response time. Partnership with TCI device maker is encouraged, but not required. Designs that can be easily integrated into all or most existing TCI devices are preferred.

PHASE I: Conceptualize, design, and build a solution to enable closed loop TCIA and test the prototype. Required Phase I deliverables will include research design, prototype with limited testing in demonstrating proof-of-concept

in vitro including performance metrics such as accuracy and sensitivity, research plans for preclinical testing, and commercialization strategy including regulatory plans. Literature and market review should be done as part of the proposal background information and not as a task to be executed during Phase I period. No animal or human use testing is to be proposed or executed during this 6-month Phase I period due to requirement of second level DoD review, which generally adds more time beyond the 6-month Phase I period. Travel should be budgeted to government site at Fort Detrick, Maryland for In Process Review at month 5 or 6 of Phase I, where results and deliverables obtained to date be presented before government subject matter experts, stakeholders, and program managers.

PHASE II: Demonstrate the proposed closed loop system in preclinical studies (i.e. relevant large animal model). Required Phase II deliverables will include design improvements to the prototype based on Phase I testing, demonstration of the solution in relevant animal model, performance metrics of the system determined, and commercialization plans including regulatory pathway for FDA clearance.

PHASE III: Phase III efforts should lead to FDA approval and be focused towards technology transition, preferably commercialization of STTR research and development. Efforts leading to FDA approval require execution of Phase II plans on commercialization and regulatory pathway, including identifying relevant patient population for clinical testing to evaluate safety and efficacy. The small business should have in plans to secure funding from non-SBIR government sources and /or the private sector to develop or transition the prototype into a viable product for sale in the military and/or private sector markets. Commercialization plans that include the private sector generally help lower cost through economy of scale.

REFERENCES:
1. Harding JN, Wilson M. Use of target-controlled infusion of propofol for military field anaesthesia. ADF Health. 2003; 4:23–26

2. Manberg PJ, Vozella CM, Kelly SD. Regulatory Challenges Facing Closed-Loop Anesthetic Drug Infusion Devices. Clin Pharmacol Ther. 2008; 84:166-169

3. Tesniere A, Servin F. Intravenous Techniques in Ambulatory Anesthesia. Anesthesiol Clin North America. 2003; 21:273-288

4. Van Poucke GE, Bravo LJB, Shafer SL. Target Controlled Infusions: Targeting the Effect Site While Limiting Peak Plasma Concentration. IEEE Trans Biomed Eng. 2004; 51:1869-1875

5. Hemmerling TM. Automated Anesthesia. Curr Opin Anaesthesiol. 2009; 22:757-763

KEYWORDS: Biosensor, Algorithm for Closed Loop Control, Sedation, Target Controlled Infusion Anesthesia (TCIA), Totally Intravenous Anesthesia (TIVA), Pain Control, Surgery, Automated Anesthesia Delivery System

DHP12-013 TITLE: Drug Delivery System for Topical Treatment of Peripheral Neuropathy

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop a controlled, target-specific delivery system for topical treatment of peripheral neuropathy.

DESCRIPTION: Peripheral neuropathy (PN) is a painful, debilitating, and often chronic condition associated with diabetes, cancer treated with various chemotherapies, and a wide variety of other diseases and conditions, such as infections, environmental/toxic exposures, alcoholism, and extremity injuries. PN is caused by damage to the small nerve fibers and may occur anywhere in the body, but is most common in the feet and lower legs. Pain symptoms may include sudden burning discomfort, electric shock-like sensation, tingling, numbness, and sensitivity to non-inducing stimuli (allodynia).

The incidence of PN in diabetes is estimated as low as 20-25% and as high as 70%. The incidence of PN is about 30-40% in cancer patients treated with some of the commonly administered chemotherapeutic agents, including cisplatin and paclitaxel. In addition to the impact of PN on individuals with diabetes and cancer, the impact of PN on military and veteran populations is significant. Deployment-related conditions put military personnel at risk of peripheral nerve injuries and many other nerve injuries resulting from trauma, blasts, and exposure to agents or environmental factors. Pain management for neuropathies is a major medical concern for military and veteran healthcare. Taken together, the prevalence of PN-associated diseases like diabetes and cancer, combined with the significant relevance to military and veteran populations, underscore the need to develop novel treatments for PN.

Currently, there is no established treatment for chemotherapy-induced PN, and only two agents (duloxetine and pregablin) are approved by the US FDA for treatment of diabetic PN. Treatment with non-steroidal anti-inflammatory drugs (NSAIDs) is common, but is limited due to nonspecificity and long-term treatment toxicities. The analgesic efficacies of several other agents in treating PN are being tested in pre-clinical studies and clinical trials. While not all-inclusive, the major categories of systemically administered treatments for PN that have recently been investigated include: 1) tricyclic antidepressants; 2) selective serotonin-norepinephrine reuptake inhibitors (SSNRIs); 3) anticonvulsants; and 4) opioids.

Considering the dose-limiting toxicities of several of these systemic treatments, topical treatment for PN is a promising, yet underdeveloped area of research and development. Topical capsaicin treatment has been investigated in diabetic patients and has shown some evidence of benefit. Topical lidocaine administered through a patch has also shown pain improvement in clinical trials done in diabetic patients. Topical treatments combining antidepressants and anticonvulsants have also recently emerged with promising findings in a clinical trial of patients with chemotherapy-induced PN. Some of the constraints and challenges of topical treatment development that need to be resolved include skin penetration and drug permeation, as well as optimum drug dosage for long periods to increase efficacy.

This topic seeks to develop a drug delivery system for a novel topical treatment for PN. The innovative approach will deliver one or more drugs through the skin and into the affected area to relieve pain. The drug delivery system should optimize efficacy and bioavailability of the treatment by integrating a target-specific and a controlled drug-release mechanism. The delivery system is also expected have no, or minimal, toxicity. The choice of drug(s) to be tested should be based on current knowledge and recent studies on PN treatment. The system should include a topical formulation that would be easily applied by the patient or caregiver.

PHASE I: Phase I work will design and develop the drug delivery system, and will use in vitro assays to test its feasibility in transporting the therapeutic through skin. Data will provide proof-of-concept that the system can be applied topically and penetrates through the skin barrier to transport and deliver the drug. An appropriate skin or skin-like model will be utilized. Parameters including optimal concentrations and topical formulation, nerve targeting capability, and controlled release will be defined. Appropriate controls will be used.

PHASE II: Phase II work will test, optimize, and validate the delivery system in animal model(s) of PN to demonstrate the analgesic effects in reducing pain. The FDA approval pathway should be outlined and considered at each developmental stage. Parameters including optimal concentrations, biological activity, toxicity, nerve targeting specificity, and controlled release will be defined. In addition, tolerability of the topical formulation on the skin will be demonstrated. Validation of success will include the marked reduction or resolution of pain in the animal model(s). During Phase II, clinical experts with insight into relevant patient populations should be consulted as the system is being fully optimized. Potential commercial and clinical partners for Phase III and beyond should be identified. Phase II technical proposals should include a detailed explanation of how the small business will obtain a monetary return on investment within two years of completion of Phase II (e.g. through sales, licensing agreements, venture capital, non-SBIR grants).

PHASE III: If successful, Phase II work will result in a novel nerve-targeted, controlled release drug delivery system to treat PN. During Phase III, additional experiments will be performed as necessary to prepare for FDA review of an IND application. A plan for protection of intellectual property should be created and executed. A detailed market analysis will be conducted, an initial clinical application for the therapeutic system will be selected, and a Phase I clinical trial will be initiated. Military application: The new therapeutic will be available to military personnel and

veterans who suffer from PN caused by deployment-related conditions, including peripheral nerve trauma, infections, and environmental agents or toxins. In addition, healthcare and quality of life for veterans with diabetes and cancer could also benefit significantly. Commercial application: Health professionals around the world could utilize this therapeutic to treat PN caused by diabetes, cancer chemotherapy, and many other conditions that cause PN.

REFERENCES:
(1) Mielke S, Sparreboom A, Mross K. 2006. Peripheral neuropathy: A persisting challenge in paclitaxel-based regimes. Eur J Cancer. 424:24-30.

(2) Pachman DR, Barton DL, Watson JC, Loprinzi CL. 2011. Chemotherapy-induced peripheral neuropathy: prevention and treatment. Clin Pharmacol Ther. 90:377-387.

(3) Smith HS, Argoff CE. 2011. Pharmacological treatment of diabetic neuropathic pain. Drugs. 71:557-589.

(4) Hartemann A, Attal N, Bouhassira D, Dumont I, et al. 2011. Painful diabetic neuropathy: diagnosis and management. Diabetes Metab, doi:10.1016/j.diabet.2011.06.003.

KEYWORDS: peripheral neuropathy, diabetes, chemotherapy, topical treatment

DHP12-014 TITLE: Development of a Biometric Model for Use in Addressing Pelvic Blast Injury

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop and validate a biometric model for use by the medical research community to address dismounted complex blast injury of the pelvis, abdomen, and genitals.

DESCRIPTION: In Afghanistan, military medical healthcare providers have expressed an interest in providing protection to soldiers to mitigate dismounted complex blast injury (DCBI). Specifically, they would like to provide protection to the pelvic floor anatomical area, the abdomen, and the genitalia during a blast event such as that seen during the explosion of an improvised explosive device (IED). The problem was outlined in Report #8 from the OPERATION ENDURING FREEDOM (OEF) Field Assistance in Science & Technology – Medical Team OEF FAST Team 04. Subject Matter Experts are in the process of collecting data to characterize the epidemiology of this event. Patient trauma data is being captured in the Joint Theater Registry (JTTR).

A Pelvic Protection Working Group (PPWG) was formed, and an abbreviated analysis of JTTR shows six soldiers were recently wounded in action and sustained pelvic injuries. At least two commercial products were identified, and an evaluation was requested. In April, 2011, the Army Research Laboratory (ARL) conducted testing using a "sand cannon." These sorts of tests provide impact forces, but do not necessarily model what anatomical and physiological damage would result.

Regional Command (South) (RC(S)) is a multi-national military group that is part of the International Security Assistance Force (ISAF) in Afghanistan. Its headquarters is located in Kandahar, Afghanistan. In May, 2011, A Joint Urgent Operational Needs Statement (JUONS) was presented to RC(S). The Project Manager, Soldier Protection and Individual Equipment (PM-SPIE) is pursuing the evaluation of potential products. The U.S. Army Research Institute of Environmental Medicine (USARIEM) Subject Matter Experts (SMEs) are planning to use a thermal manikin for an interim evaluation of commercial products.

The ARL and USARIEM models are not ideal for identifying the anatomical and physiologic damage of DCBI to the pelvis, abdomen and genitalia that may occur. They will estimate the forces transmitted, etc. and can be used to provide input data for a biometric model of the anatomy and physiology of the targeted area. A biometric model of

the anatomy and physiology of that pelvic area is needed. How well a possible protective solution performs will need to be determined using this biometric model.

PHASE I: This phase would include investigation of the epidemiology of the problem. It would include the design of a concept for the model. This feasibility study would determine the scientific, technical, and commercial merit and feasibility of a biometric model for dismounted complex blast injury of the pelvis, abdomen and genitalia. The Phase I deliverables would include the results of the epidemiology study and the feasibility study as well as a validation plan for the model. The deliverables will be used to evaluate the readiness to move the effort to Phase II.

PHASE II: This phase would include modeling and simulation of the three dimensional aspects of the anatomy and physiology of the area in question. The model would take force input (blast effect metrics), and provide some indicator of the resulting tissue disruption. The Phase II deliverables would include a demonstration of the prototype biometric model.

PHASE III: Phase III includes the technology transition to an Acquisition Programs of Record and/or commercialization of the biometric model for pelvic injury. Funding will be from non-SBIR government sources and/or the private sector to develop or transition the biometric model into a viable product or service for sale in the military or private sector markets. The end-state of this research effort is a validated biometric model of the anatomy and physiology of pelvic floor injury. There is potential commercial application in the private sector with regard to blunt trauma resulting from sports injury, and the development and design of improved personal protective sports equipment.

REFERENCES:
1. DCBITF. June 2011. Dismounted Complex Blast Injury. Report of the Army Dismounted Complex Injury Task Force. Prepared for the U.S. Army Surgeon General. http://www.armymedicine.army.mil/reports/reports.html

2. Marinescu, R. and Haden, J. 2009. "Sex/Gender Bias in Pelvic Fractures: Geometrical and Structural Analyses." Orthoworld: BoneZone. InMotion Orthopaedic Research Center.
http://www.orthoworld.com/site/orthosupplier/bonezone/online/2009/winter/editorial_marinescu.pdf

3. Shock Doctor Athletic Cup.3300 Fernbrook Lane North, Suite 250, Minneapolis, MN.
http://www.shockdoctor.com/products/cups-supporters.aspx

4. Smith, C., Sorrells, A., and Coburn, M. 2007. "Management of Urinary Retention in an Austere Environment: Suprapubic Catheter Placement." Journal of Special Operations Medicine. Volume 10, Edition 3, page 36.
http://www.socom.mil/JSOMDocs/Summer10Vol10Ed3.pdf

5. Watson, C. 2011. "Ergonomics, Design and Reliability of Body Armour." Ph. D. Thesis. Department of Engineering and Applied Science. Cranfield University. Cranfield Defense and Security.

KEYWORDS: Cadaver validation, Dismounted Complex Blast Injury, DCBI, Pelvic Injury, Abdominal Injury, Genital Injury, Personal Protective Equipment, Blast Injury, Injury Model, Blast Injury Model, Pelvic Injury Model, Body Armor, Improvised Explosive Device Injury, Pelvic Floor Injury, Blast Injury Epidemiology, Modeling and Simulation of Blast Injury, Modeling and Simulation of Body Armor, Pelvic Protection, Blast Injury, and Perineal Injury.

DHP12-015 TITLE: Objective Method for Pain Detection/Diagnosis

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: Develop an objective assay for the rapid and reliable detection/diagnosis of pain and its intensity for use with the traumatically injured including the severely cognitively impaired and sedated patients. The developed

assay may include but is not limited to biomarker, imaging, electrophysiological, and other physiological and behavioral monitoring techniques.

DESCRIPTION: A high percentage of evacuated soldiers reported experiencing severe acute pain. In a survey of 110 soldiers evacuated from Iraq to Landstuhl Regional Medical Center between July 2007 and February 2008, 60% of soldiers reported their worst pain to be severe (seven or greater on a zero to ten numeric rating scale; Buckenmaier III et al, 2009). Well managed pain in the battlefield is not only an immediate need to a suffering injured warrior but may reduce the probability of suffering from chronic pain (Perkins and Kehlet, 2000). For reasons not completely understood, many soldiers will be afflicted with chronic pain. Complicating the treatment of these patients is the high co-prevalence of chronic pain, posttraumatic stress disorder, and persistent post-concussive symptoms. Despite the numerous treatment options that have been developed for acute and chronic pain management, the treatment of pain often requires a multimodal approach that is individually tailored for the patient. The ability of health care workers to rapidly and reliably detect and measure the intensity of pain among patients that cannot reasonably "self-report" would provide a great advantage for managing pain and for the objective evaluation of treatment options.

PHASE I: Required Phase I deliverables will include identifying the measures of pain and designing the plan for practical development of the proposed assay.

PHASE II: Required Phase II deliverables will include the development, testing and demonstration of a prototype assay based on the finalized design from Phase I.

PHASE III: The contractor should identify a market for the requested effort outside of the parameters of this initiative. A commercialization plan should be described including intended market, design and fabrication requirements, marketing plan, and distribution concept.

REFERENCES:
1. Buckenmaier CC III, Rupprecht C, McKnight GM, McMillan B, White R, Gallagher RM, Polomano R, "Pain Following Battlefield Injury and Evacuation: A Survey of 110 Casualties from the Wars in Iraq and Afghanistan." 1st National Capital Region Military Research Poster Competition, Mar 2009.

2. Perkins FM, Kehlet H. Chronic pain as an outcome of surgery. A review of predictive factors. Anesthesiology. 2000 Oct;93(4):1123-33. Review.

KEYWORDS: Pain, Diagnostic, Traumatic Brain Injury, Biomarkers, Chronic Pain

DHP12-016 TITLE: Development of Technologies that Control Scar Contracture after Burn Injuries

TECHNOLOGY AREAS: Biomedical

ACQUISITION PROGRAM: Office of the Principal Assistant for Acquisition – USAMRMC

OBJECTIVE: The objective of this effort is to design a new innovative technology to intervene during the wound healing process (i.e. inflammatory, proliferative and/or remodeling stages) as to attenuate/control scar contracture and retain skin aesthetics following deep tissue burn injuries.

DESCRIPTION: Here we recognize 450,000 burn injuries requiring medical occur in the U.S. each year. Approximately 55% of 45,000 of acute hospitalizations cases require admission to specialized burn units for treatment. Burn injuries also complicate approximately 5% to 10% of contemporary combat casualties not returned to duty within 72 hours. Military combat casualties may be complicated by burn injuries that comprise deep partial thickness, or second degree burns, to full thickness, third and forth degree burns. Re-epithelialization after injury often results in the formation of scars which may subsequently lead to contracture. A contracture scar is a permanent tightening of the skin where normal elastic connective tissue is replaced with inelastic fibrous tissue. Primary skin contractures are common and are the result of the destruction of skin, subdermal fat and fascia.

Secondary contractures involve muscles and tendons and inhibit their mobility and may also result in nerve damage or degeneration. Current treatment options for scar contracture may involve over-the-counter treatments, steroid injection or even surgical intervention. The unmet needs lie in scar prevention or, in the case of scarring, the prevention of resultant scar contracture. It is envisioned that proposals will focus efforts on early intervention during the wound healing process, thereby preventing scar formation, or after scar formation has already occurred as a scar remodeling strategy.

PHASE I: Conceptualize and design an innovative solution for inhibiting scar formation or subsequent contracture following burn injuries. The required Phase I deliverables will include: 1) a research design for engineering the proposed therapeutic and 2) A preliminary prototype with limited testing to demonstrate in vitro proof-of-concept evidence (to be executed at Phase I). Other supportive data such resulting from in vivo proof-of-feasibility studies may also be provided during this 6-month Phase I period.

PHASE II: The researcher shall provide demonstration of solution in relevant animal model, performance metrics, and commercialization plans including regulatory pathway for FDA clearance design, develop, test, and demonstrate a prototype therapeutic that implements the Phase I methodology to prevent scar formation and facilitate wound healing at a burn injury site during this two year Phase II period. The researcher shall also describe in detail the plan for the Phase III effort.

PHASE III: Plans on the commercialization/technology transition and regulatory pathway should be executed here and lead to FDA clearance/approval. They include: 1) identifying a relevant patient population for clinical testing to evaluate safety and efficacy and 2) GMP manufacturing sufficient materials for evaluation. The small business should also provide a strategy to secure additional funding from non-SBIR government sources and /or the private sector to support these efforts. Military application: The desired therapy will allow military practitioners to apply the therapy. Commercial application: Healthcare professionals world-wide could utilize this product as a therapy meant to improve the standard of care presently available to burn patients.

REFERENCES:
1. "Burn Incidents Fact Sheet." American Burn Association, 2011.
http://www.ameriburn.org/resources_factsheet.php

2. "Burn Injuries." JAMA, October 28, 2009; Vol 302, No. 16; p 1828.
http://jama.ama-assn.org/content/302/16/1828.full.pdf

3. "Burns." MedLinePlus http://<http//www.nlm.nih.gov/medlineplus/burns.html

4. "Management of war-related burn injuries: lessons learned from recent ongoing conflicts providing exceptional care in unusual places." J. Craniofac. Surg., September 2010: Vol. 21, No. 5; p 1529-37.

5. "Armed conflicts and burn injuries." Ann. Burn Fire Disasters, 2005; Vol. 18; p 45-46.

6. "The elimination of post-burn scar contractures and deformities of the shoulder joint." Annals of Burns and Fire Disasters, September 2003; Vol. 16, No. 3.

KEYWORDS: partial thickness burn, scaffold, biomaterial, dermal cell migration, dermal cell incorporation, scar contracture, wound healing