
2013 Exploration Medical Capability Standing Review Panel

Research Plan Review for: *The Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities*

Final Report

I. Executive Summary and Overall Evaluation

The 2013 Exploration Medical Capability (ExMC) Standing Review Panel (from here on referred to as the SRP) participated in a site visit meeting with representatives from the Human Research Program (HRP) ExMC Element and HRP management on November 7-8, 2013 in Houston, TX to review the updated Research Plan for the Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities in the HRP Integrated Research Plan.

The updated ExMC Research Plan identified 22 active gaps which have been converted to a new format, including four that were considered Knowledge Gaps and eighteen that were considered Technology Gaps. Gaps closed prior to the latest revision (Revision E) were not included in this revision bringing the total number of active gaps from 30 identified in the 2012 SRP to the now identified 22 gaps. The SRP believes that these gaps were appropriately classified and agrees with the new format. The SRP identified and recommended new gaps, as detailed below in Section II of this report, with a key gap focused on the active integration of emerging information and procedures from other HRP Elements into the medical capabilities' deliverables and milestones. The complete list of gaps and associated tasks for each gap was clearly laid out and appropriate.

The SRP once again strongly recommends inclusion of a medical professional as a crewmember in order to achieve improved care, reduced risk, reduced cost, reduced training time, increased efficiency, and increased autonomy in exploration class missions. As detailed below in Section II, under ExMC 2.02, the SRP thinks the approach taken to evaluate quantitatively the impact of the inclusion of a physician crew medical officer to clinical outcomes in these missions is not valid. It is recommended that a more valid evaluation be developed and executed in future efforts. The SRP continues to consider this one issue as the most important and critical to the success of the ExMC Element objectives and to exploration missions in general.

In conclusion, the SRP believes that the ExMC Element is to be congratulated for an exceptional effort during this past year in upgrading, re-formatting, and achieving measurable progress within the current Research Plan. The ExMC Element addressed all the previous comments from the SRP. Particular commendation goes to Dr. Sharmi Watkins, ExMC Element Scientist, for her outstanding management, organization and integration of the multiple components and participating groups of this Element. Additionally, the SRP commends the ExMC Element for the development and progress on the following key associated work in support of the Research Plan:

- 1) The Evidence Wiki as a growing platform for collaboration and evidence sharing. Also the use of Wiki statistics to monitor and engage both national and international groups to the goals of

space exploration clinical and science efforts. 2) Addition of timelines into research plan. 3) Integration of effort and participation of other NASA centers, other discipline Elements, physicians and scientists. The SRP thinks ExMC is clearly a cohesive team all around.

II. Critique of Gaps and Tasks for the Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities

1. *Have the proper Gaps been identified to address the Risk?*
 - a. *Are all the Gaps relevant?*
 - b. *Are any Gaps missing?*
2. *Have the appropriate targets for closure for the Gaps been identified?*
 - a. *Are the interim stages appropriate to close the Gaps?*
3. *Have the proper Tasks been identified to fill the Gaps?*
 - a. *Are the Tasks relevant?*
 - b. *Are any Tasks missing?*
4. *If a Gap has been closed, does the Rationale for Gap Closure provide the appropriate evidence to support the closure?*

Gaps and Tasks:

Suggested New Gaps:

- We do not know how to integrate the emerging information and procedures from the other HRP Elements into the medical capabilities procedures, therapeutics, and outcomes.
 - There does not seem to be an active function of interaction/integration in some areas, specifically with physiology and psychophysiology. These should be looked at and treated together. These appear compartmentalized.
 - Impact of automation failure/trusting automation (Space Human Factors Engineering (SHFE)). What do you do when the automation does not work with respect to training?
 - The ExMC Element needs to work with the flight surgeons and the pharmacology discipline to know what pharmaceuticals or over the counter products are being taken.
 - Changing pathogenicity of microbes should be in the ExMC Element not just the Space Human Factors and Habitability (SHFH) and Human Health Countermeasures (HHC) Elements
 - Clinically important.
 - What happens to you and how do you deal with that?
 - Therapeutic effects.
- Microbiome to assess the effects of microgravity on this part of the body and link this information with research on how these types of changes in the microbiome can affect health.
- Use of automated smart sensors to maintain physiologic homeostasis.

ExMC 1.01: We do not know which emerging technologies are suitable for preflight medical screening for exploration missions.

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- The SRP thinks this Gap is relevant and appropriate.

Tasks:

- Cardiovascular Imaging and Strategies to Mitigate the Risk for Cardiac Events in Astronauts During Prolonged Spaceflight – PI: Benjamin Levine, Ph.D. – University of Texas Southwestern Medical Center at Dallas
- Technology Watch – Michael Krihak, Ph.D. – NASA Johnson Space Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
 - The SRP suggests contacting Monell (www.monell.org) to get more information about early diagnosis of disease by the pattern of biomarkers in breath.

ExMC 1.03: Inadequate information on the individual susceptibility to hypobaric environments (e.g. 7.2 psi lunar habitat) (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Task:

- Data Mining/Identification of Characteristics Associated with Susceptibility to Hypobaric Environments – Task Completed

ExMC 2.01: We do not know the quantified mission and crew health consequences due to medical events for exploration – class missions.

- In the description of this Gap, an “Untreated medical event” is described. The SRP recommends rewording “untreated medical event” to “partially treated”.
- The SRP would like to know what the ExMC Element is hoping to accomplish with this Gap and how they plan on dealing with the other mission profiles.
- The SRP thinks that approach outlined has parallels in the Army’s approach to risk management:
(<https://safety.army.mil/crm/COMPOSITERISKMANAGEMENTHOME/tabid/110/Default.aspx>)

Tasks:

- Integrated Medical Model (IMM) – Douglas Butler, Ph.D. – NASA Johnson Space Center
 - The SRP is pleased that as the empirical data changes the principal investigator (PI) will update their model to ensure it is 95% confident.
 - The PI should stay abreast of all data and updates.
 - This is not a static model so as more data is collected it will fold into the model.
 - The model should not be based on only Low Earth Orbit (LEO) data; the PI should extrapolate data from expedition missions.
- Integrated Medical Model - Chest Injury Module – Task Completed
- Integrated Medical Model - Head Injury Module – Task Completed
- Integrated Medical Model - Abdominal Injury Module – Task Completed
- Integrated Medical Model - Bayesian Analysis – Task Completed
- Integrated Medical Model - Neck Injury Module – Task Completed
- Probabilistic Analysis of Renal Stones in US Astronauts – PI: Jerry Myers, Ph.D. –

NASA Glenn Research Center

- Data Request for Sleep - Deprivation Medical Intervention Forecasting (SDMIF) – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center

ExMC 2.02: We do not know how the inclusion of a physician crew medical officer quantitatively impacts clinical outcomes during exploration missions.

- The SRP thinks that the 210 day exploration mission profile should be re-evaluated (the requirement for a physician or physician’s assistant should be a function of the time needed to obtain definitive medical care).

Tasks:

- Quantify Impacts of Physician Training on Medical Task Performance – Devon Griffin, Ph.D. – NASA Glenn Research Center
 - **This is not what the SRP was asking for; please refer to all prior Final Reports from the ExMC SRP Reviews.**
 - The SRP does not think this was well described in the presentation.
 - This is not a valid evaluation of physician.
 - The SRP strongly disagrees in selecting three manual tasks to assess value of physician in missions of long-duration. The SRP strongly recommends that clinical scenarios, not isolated manual skills, be used to evaluate inclusion of a physician crew medical officer in determining impact to clinical outcomes during exploration missions.
 - The person needs good clinical judgment and clinical knowledge of how to make decisions, not just possessing knowledge and having capability to perform tasks.
 - Collective activity of dealing with a scenario.
 - The SRP suggests looking at the U.S. Army where analogs are similar
 - <https://ccc.amedd.army.mil/> : (POC: Dr. Victor Convertino, USARMY, MEDCOM Army Institute of Surgical Research, 3698 Chambers Pass, Bldg 3611, Fort Sam Houston, TX 78234-6315; Tel.: 210-539-5633; Victor.a.convertino@mail.mil)
 - The Army has found that fully validated mission scenarios are very useful.
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – Michael Krihak, Ph.D. – NASA Johnson Space Center
- Long-Duration Cross-Training Feasibility and Methods – Planned Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Task Completed

ExMC 3.01: We do not know the optimal training methods for in-flight medical conditions identified on the Exploration Medical Condition List taking into account the crew medical officer’s clinical background (CLOSED)

- The SRP thinks the rationale for closing this Gap is not appropriate.
- The SRP recommends that there should be a mission requirement that prior to the mission, the clinician should continue training for proficiency not Just-In-Time (JIT) training (pre and during flight).
- The SRP thinks that training, specifically geared to making sure there is no degradation

of skills, should be added.

Tasks:

- Medical Training Methods for Exploration Missions – Task Completed
- Evaluation of Task-Skill-Knowledge JIT techniques for medical and other emergency events - Planned Task
- Medical Proficiency Training – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – Michael Krihak, Ph.D. – NASA Johnson Space Center
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Task Completed

ExMC 3.02: Lack of knowledge about the current state of the art in telementoring/telemedicine as a tool for assisting crewmembers to diagnose and treat medical conditions that occur in space flight (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Data Mining for Telementoring Studies and Practices – Task Completed
- Telemedicine Workshop – Task Completed

ExMC 3.03: We do not know which emerging technologies are suitable for in-flight screening, diagnosis, and treatment during exploration missions.

- The SRP thinks that it is important to remember that when software is concerned, the timelines are linear, but computational speed and software development is geometric, which results in poor predictive value.
- If the decision support software is not Federal Drug Administration (FDA) approved, it should have at least have IRB approval.
- The SRP suggests contacting the individuals below because technologies are being developed at the National Science Foundation (NSF)-sponsored Nanosystems Engineering Research Center (NERC) for Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST) (assist.ncsu.edu) that may be relevant. The point of contacts (POCs) at NCSU and NSF are: Veena Misra Director, NSF ASSIST Nanosystems Center (http://www4.ncsu.edu/~vmisra/Veena_Misra/Home.html) and D. Keith Roper, NSF, Division of Engineering Education and Centers, (703) 292-8769.
- The SRP thinks that regarding the need for “Multi-purpose technologies that can be used for both the evaluation and treatment of crew members are desired” (page 58 of the ExMC presentation); speech/voice analysis may provide useful insights into the psychological state of crewmembers. The SRP recommends contacting the MIT Lincoln Laboratory which has been very active in this area (www.ll.mit.edu/; POC: Dr. Jeffrey S. Palmer).

Tasks:

- Determine Requirements for In-Flight Periodic Health Status Exams Based on Space

Medicine Exploration Medical Condition List – Task Completed

- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – Michael Krihak, Ph.D. – NASA Johnson Space Center
- Data Sharing Activity to Gather Evidence for Impaired Healing Risk – Planned Task

ExMC 4.01: We do not have the capability to provide a guided medical procedure system that integrates with the medical system during exploration missions.

- If this Gap remains a standalone Gap, the SRP thinks it needs to be more robust (similar to Gap 5.01).
- The SRP thinks that personalized medicine should be included. The personalized medicine should include:
 - History
 - Genetic information can be included here as it becomes available and vetted for predictive value.
 - Decision support software.

Tasks:

- Assisted Medical Procedures (AMP) – PI: Victor Hurst, Ph.D. – NASA Johnson Space Center
 - The SRP thinks this task needs to be more robust.
 - The SRP thinks treatment should be personalized and a way to do this is to include factors like individual sensitivity to treatment and individual preference.
 - The SRP thinks this is a bold project and NASA will help the community if this work is successful.
- Integration of iRevive with the Lightweight Trauma Module – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – Michael Krihak, Ph.D. – NASA Johnson Space Center
- Information Integration for Electronic Procedures – Planned Task
- Advanced Concepts for Information Integration and Presentation – Planned Task
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Completed Task

ExMC 4.02: We do not have the capability to provide non-invasive medical imaging during exploration missions.

- Are there other clinical uses for ultrasound and if so, have they been considered?
- Pre-flight data download of each individual/astronaut.
- Add an additional target for closure.
- More technology watch and empirical data because it is not clear that ultrasound is a good for treatment of bone.
- The SRP thinks that if there are not already, there should be individualized, anatomical, virtual astronauts for each astronaut. This would allow you to have no user variability.
- The SRP thinks that an alternate approach, in those instances where MRI and/or CT scans are not feasible, would be to create virtual astronauts using dual energy X-ray absorptiometry (DXA) and laser surface scan data.
- The SRP thinks that if not already, endoscopic ultrasound should be considered.

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- The SRP also recommends getting more information about Google Glass, which is a wearable computer with an optical head-mounted display that displays information in a smartphone-like hands-free format in one's field of vision, takes pictures and communicates with the Internet via voice commands, head tilts, and a touchpad.

Suggested New Task:

Magnetic Resonance Imaging (MRI) or computed tomography (CT) Scan for each astronaut on Earth (pre-flight total body images). This pre-flight imaging modality should be uploaded into software that can superimpose ultrasound images that are captured later during a space mission for combined modality viewing.

- As ultrasound seems to be the ideal imaging modality for inflight missions, its efficacy and accuracy can be highly enhanced with the use of image-merging techniques from a conceivable library of pre-flight total body MRI and CT imaging for each individual. Though true augmented reality remains challenging in medical applications, cross-modality imaging merging has proven to be highly mathematically accurate in recent projects at the University of California, Los Angeles (funded by the National Institutes of Health). This type of image merging has the potential to eliminate many of the real-time user errors and other limitations that ultrasound alone presents in a mission environment.

Tasks:

- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – Task Completed
 - Intuitive Ultrasound Catalog for Autonomous Medical Care – Task Completed
 - Flexible Ultrasound System – PI: William Thompson, Ph.D. – NASA Glenn Research Center
 - Ultrasound Fracture Diagnosis in Space – Task Completed
 - Validation of On-Orbit Methodology for the Assessment of Cardiac Function and Changes in the Circulating Volume Using Ultrasound and Braslet-M Occlusion Cuffs, SDTO 17011 U/R – Task Completed
 - Wideband Single Crystal Transducer for Bone Characterization – PI: Kevin Snook, Ph.D., TRS Ceramics, Inc.
 - Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
 - Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
 - Multi-Use Near-Infrared Spectroscopy System for Spaceflight Health Applications – PI: Gary Strangman, Ph.D. – Harvard Medical School
 - Portable Quantitative Ultrasound with DXA/QCT and FEA Integration for Human Longitudinal Critical Bone Quality Assessment – PI: Yi-Xian Qin, Ph.D. – Stony Brook University
 - The SRP thinks this would be very beneficial especially if it could be used to help screen for osteoporosis in-flight.
 - Prevention of Renal Stone Complications in Space Exploration – Michael Bailey, Ph.D. – University of Washington
- Non-Invasive Monitoring of Intracranial Pressure (ICP) with Volumetric Ophthalmic Ultrasound – PI: Aaron Dentinger, Ph.D. – General Electric Company
- The SRP thinks that this is a very interesting task and could possibly be used clinically to detect thickening of the retina (diagnosis of diabetic retinopathy).

ExMC 4.04: We do not have the capability to deliver supplemental oxygen to crew members while minimizing local and cabin oxygen build-up during exploration missions.

- The SRP suggests looking at a hybrid: a recycling system and concentrator (deliver it without increasing compartment oxygen).
- The SRP suggests a closed-circuit breathing apparatus (Rebreather) (<http://en.wikipedia.org/wiki/Rebreather>) which are used in a variety of circumstances, e.g., technical diving, hazmat mission (typical equipment: http://www.draeger.com/sites/enus_us/Pages/Fire/PSS-BG-4-plus.aspx?navID=393), and apparently as part of the Primary Life-Support System (PLSS) http://www.nasa.gov/pdf/188963main_Extravehicular_Mobility_Unit.pdf. The rebreather technology can be used to provide supplemental oxygen without dumping oxygen to the local environment (see: Pollack et al., *Wilderness and Environmental Medicine*, 2007; 18:86-94).

Tasks:

- Development of Pressure Swing Adsorption Technology for Spaceflight Medical Oxygen Concentrators – PI: James Ritter, Ph.D. – University of South Carolina
- Evaluation of Oxygen Concentrators at Altitude – Task Completed
- Medical Oxygen Fire Safety – Task Completed
- Portable Cathode-Air-Vapor-Feed Electrochemical Medical Oxygen Concentrator – Task Completed
- Oxygen Delivery System – PI: Sandra Olson, Ph.D. – NASA Glenn Research Center
- Lightweight Trauma Module – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.05: We do not have the capability to measure laboratory analytes in a minimally invasive manner during exploration missions.

- The SRP thinks that this Gap should be a global Tech Watch.

Tasks:

- In-flight Blood Analysis Technology for Astronaut Health Monitoring – Task Completed
- Nanoscale Test Strips for Multiplexed Blood Analysis – Task Completed
- Reusable Handheld Electrolytes and Lab Technology for Humans – Task Completed
- Exploration Laboratory Analysis - PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
 - The SRP does not understand why this has to be painless and recommends looking for an alternate, less painful site.
- Cell Phone-based Lateral Flow Assay for Blood Biomarker Detection – PI: Reuben Sandler, Ph.D. – Intelligent Optical Systems, Inc.
 - The SRP thinks that this could be used for abnormal blood cell detection using a peripheral device for a smartphone.

ExMC 4.06: We do not have the capability to stabilize bone fractures and accelerate fracture healing during exploration missions.

- The SRP thinks this Gap is relevant and appropriate.

Tasks:

- Combined Scanning Confocal Ultrasound Diagnostic and Treatment System for Bone Quality Assessment and Fracture Healing – Completed Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
 - Hydrogel encapsulated bone
- Development of capability to treat bone fractures – Planned Task
 - The SRP recommends not narrowing down so much now that you may miss all things that need to heal (not just fractures).
 - The SRP also recommends not just limiting the study to looking at the wrist.
- Portable Quantitative Ultrasound with DXA/QCT and FEA Integration for Human Longitudinal Critical Bone Quality Assessment – PI: Yi-Xian Qin, Ph.D. – Stony Brook University

ExMC 4.07: Limited wound care capability to improve healing following wound closure (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.08: We do not have the capability to optimally treat musculoskeletal injuries during exploration missions.

- The SRP recommends not trying to reinvent something that may already exist and to look at a simple solution instead of a device (Pilates substitute, exercise bands).
- The SRP thinks it is good that the ExMC Element is integrating with the HHC exercise discipline.

Tasks:

- Development of Methods/Technologies for Treating MLT Injuries – Planned Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- Risk of Intervertebral Disc Damage After Prolonged Spaceflight – PI: Alan Hargens, Ph.D. – University of California, San Diego
- Sonographic Astronaut Vertebral Examination – PI: Scott Dulchavsky, M.D., Ph.D. – Henry Ford Health System

ExMC 4.09: We do not have the capability to provide medical suction and fluid containment during exploration missions.

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- The SRP thinks the concept of fluid recycling should be considered for reuse in the cell saver.

Tasks:

- Development of Medical Suction Technology – PI: John McQuillen, Ph.D. – NASA Glenn Research Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.10: Lack of rapid vascular access capability for space flight (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Intraosseous (IO) Access Device Demonstration – Task Completed

ExMC 4.11: Limited dental care capabilities (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Development of Methods/Technologies for Dental Conditions – Completed Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.12: We do not have the capability to generate and utilize sterile intravenous fluid from potable water during exploration missions.

- The SRP thinks that manufacturing and administering fluids should be separated into two efforts.
- Pall filters for bacteria, but does it filter for viruses?
- Is the system testing for pyrogens?
- The SRP thinks that this is a potentially useful technology and a possible Tech Watch candidate (“Recent advances in biosensor based endotoxin detection.” Biosens Bioelectron. 2014 Jan 15;51:62-75. doi: 10.1016/j.bios.2013.07.020. Epub 2013 Jul 20. Das AP, Kumar PS, Swain S. Bioengineering Laboratory, Centre of Biotechnology, Siksha O Anusandhan University, Bhubaneswar, India.)

Tasks:

- Development of Capability for Algorithm-based Fluid Resuscitation – Planned Task
 - The SRP suggests moving this to the ExMC Assisted Medical Procedures (AMP) (Task in ExMC 4.01).
 - The SRP thinks that the conditions for this would need to be known in order to develop an algorithm.
- Intravenous Fluid GENERation for Exploration Missions – Task Completed
- IVGEN Gap Analysis – PI: John McQuillen, Ph.D. – NASA Glenn Research Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.13: We have limited capability to screen for, diagnose, and treat renal stones during exploration missions.

- The SRP recommends that the ExMC Element first understand more about renal stone formation with studies and factors that cause them before it worries about treatment.
- The SRP suggests reevaluating the interim stages and metrics for renal stones.
- The SRP thinks the astronauts should be directed to drink the required amount of fluid to help prevent renal stones.
- The SRP thinks that lithotripsy is not appropriate for a space mission because of possible side effects.
- The SRP also thinks that there may be some value in providing an expeditionary or post-mission method for capturing stones for analysis.

Tasks:

- Smart Therapeutic Ultrasound Device for Mission-Critical Medical Care – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Task Completed
- Prevention of Renal Stone Complications in Space Exploration – Michael Bailey, Ph.D. – University of Washington

ExMC 4.14: We do not have the capability to track medical inventory in a manner that integrates securely with the medical system during exploration missions.

- The ExMC Element should consider integration with the pharmacology discipline.
- The SRP thinks that self-reported diaries are not always accurate.
- The SRP thinks that medical information must become disclosed in case of emergency.
- New technology of ultra-low power electronics from NSF-sponsored Nanosystems Engineering Research Center (NERC) for Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST) (assist.ncsu.edu/01580) that allow ubiquitous monitoring (discussed with Patrick Fink) (see contact information at NCSU, NSF and MIT LL provided in Gap 3.03).
- PROTEUS technology delivering a digestible chip embedded onto pills which can be tracked by an external monitor (<http://proteusdigitalhealth.com/>).

Tasks:

- Medical Consumables Tracking- GRC – PI: John Zoldak, Ph.D. – NASA Glenn Research Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.15: Lack of medication usage tracking system that includes automatic time stamping and crew identification (content of this Gap has been merged with ExMC Gap 4.14)

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- The SRP thinks that these Gaps should be separated back out.

Tasks:

- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.16: Lack of technique or procedure to draw injectable medication into a syringe without bubble formation or bubble removal prior to medication delivery (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Air/Fluid Separation in a Syringe in a Microgravity Environment – Task Completed

ExMC 4.17: We do not have the capability to package medications to preserve stability and shelf-life during exploration missions.

- Is HRP looking at formulation or just packaging? Even though the HHC Element is looking at formulation, formulation may be a factor for the ExMC Element to consider as well. Unit dose injections can be given via pens which are easier to use than needles and syringes.
- The SRP recommends looking at U.S. Army because they have experience packaging rations for long term storage which may be helpful:
<http://nsrdec.natick.army.mil/media/fact/food/PIT.pdf>

Tasks:

- Development of Capability to Protect Medications in Spaceflight - Planned Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- Packaging Tech Watch – Planned Task
- Evaluation of Packaging Materials and Methods for Improved Medication Stability – Planned Task
- Medication Stability Analysis: Method – Planned Task

ExMC 4.18: Limited biomedical monitoring capability for exploration extravehicular activity suits (content of this Gap has been merged with ExMC Gap 4.19)

- The SRP thinks the merging of this Gap with ExMC 4.19 is appropriate.

Tasks:

- Biomedical Sensors (EVA) ARC – Task Completed
- Noninvasive Biosensor Algorithms for Continuous Metabolic Rate Determination – Task Completed.
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.19: We do not have the capability to monitor physiological parameters in a minimally invasive manner during exploration missions.

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- The SRP recommends looking at the work in this area that is actively done outside of NASA by other groups (NSF, North Carolina State University, University of Massachusetts center for personalized health, Massachusetts Institute of Technology Wearable Lab, Lincoln Lab) <http://www.fool.com/investing/general/2013/12/02/news-wearable-tech-market-to-hit-8-billion-this-ye.aspx>
 - Please see contact information for NSF, NCSU ASSIST Center, and MIT Lincoln Lab provided in Gap 3.03 comments. Also: The University of Massachusetts Amherst POC: Dr. James Capistran, capistran@umass.edu, U.S. Army Research Institute of Environmental Medicine (USARIEM) Natick, MA
 - Accelerometers are not mentioned.
 - The ExMC Element should monitor the astronaut's blood pressure and evaluate it from a clinical point of view.
 - The SRP thinks that the “select and develop...” language is unclear.
 - The development of Ultra-low power wearable System on a Chip (ULPW SoC) technology is relevant to NASA's mid- to long-term needs. See: Army SBIR Topic Number: A14-052 (Army) Title: Ultra Low-Power System on a Chip (SoC) for Physiological Status Monitoring (PSM): http://www.dodsbir.net/sitis/display_topic.asp?Bookmark=44800

Tasks:

- Lightweight, Wearable Metal Rubber-Textile Sensor for In-Situ Lunar Autonomous Health Monitoring – Task Completed
- Lunar Health Monitor: A Wearable System to Monitor Astronaut Health Status – Task Completed
- Wearable Health Monitoring Systems – Task Completed
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- Biosensors for Exploration Medical System – PI: Fritz Moore, Ph.D. – NASA Ames Research Center
- Biomedical Sensors (EVA) ARC – Task Completed

ExMC 4.21: We do not have a reusable, single-operator capability to irrigate the eyes during exploration missions.

- The SRP suggests integrating this with the suction system to conserve fluids.

Tasks:

- Development of Methods/Technologies for Eye Wash Capability – Planned Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.22: Limited capability to diagnose and treat radiation sickness (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center

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- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.23: We do not have the capability to auscultate, transmit, and record body sounds during exploration missions.

- The SRP agrees that this is a continuous problem because the current (ISS) environment is noisy and it can be assumed that the next exploration vehicle may be as well. For that reason, the SRP recommends not closing this Gap because there are always new products

Tasks:

- JAXA Auscultation Data Review – PI: Doug Ebert, Ph.D. – NASA Johnson Space Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.24: Lack of knowledge regarding the treatment of conditions on the Space Medicine Exploration Medical Condition List in remote, resource poor environments (CLOSED)

- The SRP thinks the rationale for closing this Gap is appropriate.

Tasks:

- Research Treatment of Relevant Medical Conditions in Remote, Resource Poor Environments – Completed Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center
- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Task Completed

ExMC 4.25: We do not have the capability to deliver injectable medication to a suited crewmember during exploration missions.

- The SRP thinks this Gap is relevant and appropriate.

Tasks:

- Spaceflight Injectable Delivery System – PI: Aaron Weaver, Ph.D. – NASA Glenn Research Center
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.26: We do not have the capability to screen for, diagnose, and treat disease due to dust exposure during exploration missions.

- The SRP thinks this Gap is relevant and appropriate.

Tasks:

- Development of methods/technologies to monitor and treat disease caused by non-terrestrial dust exposure – Planned task
- LADTAG Lunar Dust Health Standard – PI: John James, Ph.D. – NASA Johnson Space Center

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- Review and Assess State of Knowledge Regarding the Acute or Chronic Cardiovascular Toxicity of Mineral Dusts – Planned task
 - Clearance of Particles Depositing in the Human Lung in Low-Gravity – Completed Task
 - Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
 - Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 4.27: We do not have the capability to sterilize medical equipment during exploration missions.

- The SRP thinks this Gap is relevant and appropriate.

Tasks:

- Development of Capability to Sterilize Medical Equipment in Spaceflight – Planned Task
- Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
- Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

ExMC 5.01: We do not have the capability to comprehensively manage medical data during exploration missions.

- The SRP recommends changing this Gap to “We do not have the capability to comprehensively manage and mitigate medical data during exploration missions
- The relationship and integration between AMP (Gap 4.01) and this system should be more clearly defined and ranked.
- The SRP thinks it is commendable that the ExMC Element is using an open architecture system that allows flexibility that could otherwise be lacking.
- The SRP thinks the ExMC Element should also be careful about security (e.g., HIPPA concerns) because it is an open system (an open-architected system is not necessarily less secure than a proprietary system).
- This approach also allows them to accommodate new emerging technologies

Tasks:

- Exploration Medical System Demonstration – PI: David Rubin, Ph.D. – NASA Johnson Space Center
- Middleware for Exploration Medical System – PI: David Rubin, Ph.D. – NASA Johnson Space Center
- Electronic Medical Records for Exploration Medical Records – PI: David Rubin, Ph.D. – NASA Johnson Space Center
- Biosensors for Exploration Medical System – PI: Fritz Moore, Ph.D. – NASA Ames Research Center
- Exploration Dental Imaging Capabilities for Exploration Medical System – PI: David Rubin, Ph.D. – NASA Johnson Space Center
- Distributed System for Spaceflight Biomedical Support – PI: Gary Strangman, Ph.D. - Massachusetts General Hospital
- Assisted Medical Procedures – PI: Victor Hurst, Ph.D. – NASA Johnson Space Center
- Exploration Medical System Demonstration (EMSD) Baseline Capability Evaluation using the Habitation Development Unit (HDU) – Task Completed

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- ExMC Support of Medical Scenarios for the Autonomous Mission Operation (AMO) Test – Task Completed
 - Human Research Wiki – PI: Jack Rasbury – NASA Johnson Space Center
 - Technology Watch – PI: Michael Krihak, Ph.D. – NASA Johnson Space Center

III. Discussion on the strengths and weaknesses of the IRP and identify remedies for the weaknesses, including answering these questions:

Is the Risk addressed in a comprehensive manner?

- The SRP thinks the risk is addressed in a comprehensive manner and that the ExMC Element is doing everything that should be done (data mining, mission exposure).

Are there obvious areas of potential integration across disciplines that are not addressed?

- The ExMC Element appears to have done this very well with the HHC Element, the SHFH Element, the Behavioral Health and Performance Element, and medical operations. Additional integration, specifically with the pharmacology discipline, is recommended.

IV. Evaluation of the progress in the IRP since the 2012 SRP meeting

- Considering that there is no true mission driver for deadlines, it is very impressive that the ExMC Element can estimate a timetable to close the Gaps, although it may not be accurate.
- The ExMC Element has responded well to prior comments by the SRP.

V. Additional Comments

- “Student program” implies college age students but they are actually fellows, medical students, residents, etc. The ExMC Element may want to consider changing name of this program.
- There are a lot of engineers in the ExMC Element, but not a lot of clinicians and medical doctors. The ExMC Element is operational medicine and they may want to include more critical care or intensive care unit nurses into the “student” program.
- The SRP thinks that it would be helpful to have references and an acronym definition page in future SRP reviews.

VI. Response to the Addendum Question

Each gap and task within the ExMC Research Plan has been assigned a priority (high, medium, or low) by the ExMC Advisory Group. The Advisory Group is comprised of ExMC’s stakeholders and includes flight surgeons, astronauts, and medical hardware personnel. Charge to panel: Please review the gap and task priorities for Fiscal Year 2014 and provide comments regarding recommended changes to these priorities.

*** The HRP acknowledges that any recommendations or comments to the Statement of Task Addendum will be based only on the scientific and technical data provided. A full prioritization cannot be completed by the SRP without other data that has not been provided, such as, budget and schedule constraints. Each gap within the ExMC research plan is reviewed annually and*

assigned a priority (high, medium, or low) by the ExMC.

The updated ExMC research plan identified 22 active gaps. The SRP believes that these gaps have been appropriately classified and prioritized. The appropriate targets for gap closure have been identified with the few exceptions addressed in Section II of this document.

VII. 2013 Exploration Medical Capability SRP Research Plan Review (WebEx): Statement of Task for the Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities

The 2013 Exploration Medical Capability (ExMC) Standing Review Panel (SRP) is chartered by the Human Research Program (HRP) Chief Scientist. The purpose of the SRP is to review the ExMC Element's section of the current version of the HRP's Integrated Research Plan which is located on the Human Research Roadmap (HRR) website (<http://humanresearchroadmap.nasa.gov/>). Your report will be provided to the HRP Chief Scientist and will also be made available on the HRR website.

The 2013 ExMC SRP is charged (to the fullest extent practicable) to:

1. Based on the information provided in the current version of the HRP's IRP, evaluate the ability of the IRP to satisfactorily address the Risk by answering the following questions:
 - A. Have the proper Gaps been identified to address the Risk?
 - i) Are all the Gaps relevant?
 - ii) Are any Gaps missing?
 - B. Have the appropriate targets for closure for the Gaps been identified?
 - i) Are the interim stages appropriate to close the Gaps?
 - C. Have the proper Tasks been identified to fill the Gaps?
 - i) Are the Tasks relevant?
 - ii) Are any Tasks missing?
 - D. If a Gap has been closed, does the Rationale for Gap Closure provide the appropriate evidence to support the closure?
2. Identify the strengths and weaknesses of the IRP, *and* identify remedies for the weaknesses, including answering these questions:
 - A. Is the Risk addressed in a comprehensive manner?
 - B. Are there obvious areas of potential integration across HRP disciplines that are not addressed?
3. Please evaluate the progress in the IRP since your 2012 SRP meeting.
4. Please comment on any important issues that are not covered in #1, #2, or #3 above. If addendum questions are provided in section X below, please address each of the questions as fully as possible.

Additional Information Regarding This Review:

1. Expect to receive review materials at least four weeks prior to the meeting.

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2. Participate in a 2013 ExMC SRP conference call to discuss any issues, concerns, and expectations of the review process approximately three weeks prior to the meeting.
 - A. Discuss the 2013 ExMC SRP Statement of Task and address questions about the SRP process.
 3. Attend the 2013 ExMC SRP meeting at NASA JSC on November 7 – 8, 2013.
 - A. Attend Element or Project presentations, question and answer session, and briefing.
 - B. Prepare a draft report that addresses each of the evaluation criteria listed in the panel charge. Debrief the HRP Chief Scientist and a representative from the ExMC Element on the salient points that will be included in the final report and specifically the items in the panel charge.
 4. Prepare a draft final report (within one month of the site visit debrief) that contains a detailed evaluation of the current IRP specifically addressing items #1, #2, #3, and #4 of the SRP charge. The draft final report will be sent to the HRP Chief Scientist and he will forward it to the appropriate Element for their review. The ExMC Element and the HRP Chief Scientist will have 2 business days to review the draft final report and identify any misunderstandings or errors of fact and then provide official feedback to the SRP. If any misunderstandings or errors of fact are identified, the SRP will have 10 business days to address them and finalize the 2013 SRP Final Report. The 2013 SRP Final Report will be submitted to the HRP Chief Scientist and copies will be provided to the ExMC Element and also made available to the other HRP Elements. The 2013 SRP Final Report will be made available on the HRR website (<http://humanresearchroadmap.nasa.gov/>).

Addendum to the Charge:

Each gap and task within the ExMC research plan has been assigned a priority (high, medium, or low) by the ExMC Advisory Group. The Advisory Group is comprised of ExMC’s stakeholders and includes flight surgeons, astronauts, and medical hardware personnel.

Charge to panel: Please review the gap and task priorities for Fiscal Year 2014 and provide comments regarding recommended changes to these priorities.

**The HRP acknowledges that any recommendations or comments to the Statement of Task Addendum will be based only on the scientific and technical data provided. A full prioritization cannot be completed by the SRP without other data that has not been provided, such as, budget and schedule constraints. Each gap within the ExMC research plan is reviewed annually and assigned a priority (high, medium, or low) by the ExMC.

VIII. ExMC Standing Review Panel Roster

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