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Conceptual Drivers for an Exploration Medical System

Erik AntonsenNASA, USA, erik.l.antsen@nasa.gov**Co-Authors**Andrea Hanson, NASA, USA, andrea.m.hanson@nasa.govRonak Shah, KBRwyle, USA, ronak.shah@nasa.govRebekah Reed, NASA, USA, rebekah.d.reed@nasa.govMichael Canga, NASA, USA, michael.a.canga@nasa.gov**Abstract**

Interplanetary spaceflight, such as NASA's proposed three-year mission to Mars, provides unique and novel challenges when compared with human spaceflight to date. Extended distance and multi-year missions introduce new elements of operational complexity and additional risk. These elements include: inability to resupply medications and consumables, inability to evacuate injured or ill crew, uncharted psychosocial conditions, and communication delays that create a requirement for some level of autonomous medical capability. Because of these unique challenges, the approaches used in prior programs have limited application to a Mars mission. On a Mars mission, resource limitations will significantly constrain available medical capabilities, and require a paradigm shift in the approach to medical system design and risk mitigation for crew health. To respond to this need for a new paradigm, the Exploration Medical Capability (ExMC) Element is assessing each Mars mission phase—transit, surface stay, rendezvous, extravehicular activity, and return—to identify and prioritize medical needs for the journey beyond low Earth orbit (LEO). ExMC is addressing both planned medical operations, and unplanned contingency medical operations that meld clinical needs and research needs into a single system. This assessment is being used to derive a gap analysis and studies to support meaningful medical capabilities trades. These trades, in turn, allow the exploration medical system design to proceed from both a mission centric and ethics-based approach, and to manage the risks associated with the medical limitations inherent in an exploration class mission. This paper outlines the conceptual drivers used to derive medical system and vehicle needs from an integrated vision of how medical care will be provided within this paradigm.

Keywords: (Max 6 keywords: exploration, medicine, spaceflight, Mars, research, NASA)

I. BACKGROUND

NASA has over four decades of experience in human spaceflight. Since 1961, over 400 men and women have travelled into space, most into low Earth orbit (LEO). In the Skylab, Shuttle-MIR, and International Space Station (ISS) programs, NASA developed an evidence base for human health in “long duration” missions of over three weeks[1]. Today, NASA is planning for missions of over three years. With such great distance and duration, Mars missions are completely outside the scope of NASA's human spaceflight experience. As a result, we are developing new strategies that are not reliant on existing assumptions.

The current model of ISS LEO operations depends on real-time communications, regular resupply capability, and the possibility of evacuation in the case of medical emergencies. For a Mars mission, the delivery of medical care must be re-imagined to allow

scoping of a system that will support crew and mission needs in a remote and isolated environment. The task of developing this new medical system rests with the Exploration Medical Capability (ExMC) element of NASA's Human Research Program (HRP).

HRP is tasked with decreasing the risks to human spaceflight through research investment. Specifically the goals of HRP are “to provide human health and performance countermeasures, knowledge, technology, and tools to enable safe, reliable, and productive human space exploration.” [2]. To reach this goal and enable a human Mars mission presents a unique challenge that requires an applied research program. This is different from other models of research and development in two ways. First, an applied research program has a specific goal: to improve the operational capabilities crew have in a mission at some defined point in the future. In order to meet that goal, a conceptual basis for research investments must be structured toward the desired

endpoint. Second, an applied research program is unable to provide an ongoing commitment to specific lines of inquiry. As new information is understood, the odds of success of a particular investment must be constantly weighed against other benefits and investments. In the context of providing medical care in the face of unknown challenges in a new mission, this ever-shifting prioritization becomes manageable through a structured approach to risk and development.

ExMC is the HRP element tasked with decreasing the medical risks in human spaceflight. All HRP Elements interface with the Human System Risk Board (HSRB). This Board uses a Continuous Risk Management (CRM) framework for approximately 30 risks identified by NASA as critical to enabling human spaceflight. The HSRB and this process are described in detail elsewhere [3]. ExMC has traditionally been tasked with addressing a single HSRB risk:

“Given that medical conditions/events will occur during human spaceflight missions, there is a possibility of adverse health outcomes & decrements in performance in mission and for long term health.” [2]

To address this risk, ExMC charters research projects, funds technology development, and interfaces with intra- and extra-agency resources. In 2015, ExMC was restructured to update its research plan and to better align with agency operational goals. Today, ExMC is focused on the creation of a vehicle-integrated medical system designed to meet exploration mission needs.

Motivation

In 2001, the Committee on Creating a Vision for Space Medicine During Travel Beyond Low Earth Orbit delivered a report to NASA entitled, Safe Passage: Astronaut Care for Exploration Missions [4]. This committee acted on authority of the Institute of Medicine to: 1) Assess what is known about the effects of space travel on health; and 2) Suggest how health care during space travel might be approached. The recommendations from this report formed the conceptual basis for the current workings of the HRP. In the fifteen years since Safe Passage was published, some of its recommendations have been implemented in LEO. Much work remains to extend its vision to exploration through the merging of engineering requirements and medical priorities in the context of ongoing technological development.

As Safe Passage suggests, NASA’s exploration goals will require a comprehensive health care system

built on a strategic research plan. The Safe Passage Report is organized into seven chapters that each offer key conclusions with recommendation. Chapters 2 and 6 are of particular significance to the conceptual drivers for an exploration medical system. All of the key elements in the committee’s recommendation are listed in Figure 1.

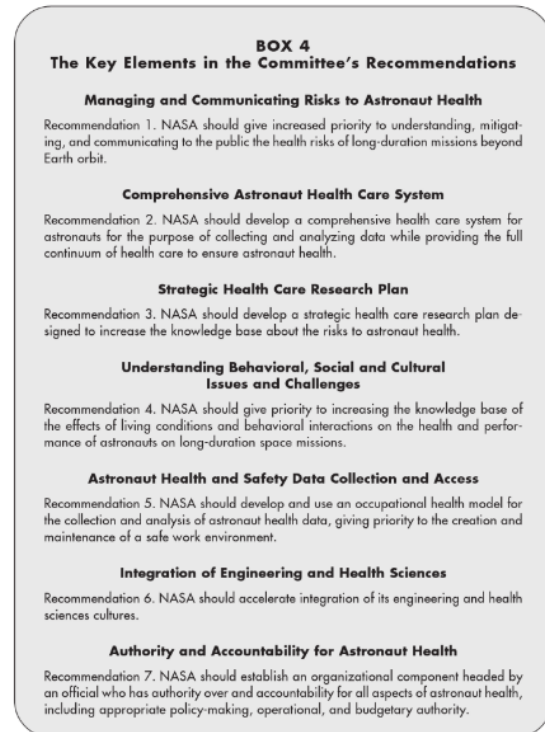


Figure 1: Recommendations for a Human Centric forward path from the Institute of Medicine report Safe Passage.

Some specific observations from Safe Passage bear note:

From Conclusion 2:

“Currently, there is no comprehensive and inclusive strategy to provide optimum health care for astronauts in support of long-duration missions beyond low Earth orbit, nor is there sufficient coordination of health care needs with the engineering aspects of such missions.”

From Conclusion 6:

“The human being must be integrated into the space mission in the same way in which all other aspects of the mission are integrated.”

NASA has made a number of strides towards rectifying these issues since Safe Passage was published. Planning for a Mars mission makes solving them more critical.

In 2006, the National Research Council published *A Risk Reduction Strategy for Human Exploration of Space: A Review of NASA's Bioastronautics Roadmap* [5]. The NRC identified Human Systems Integration as cross-cutting risk for all planned design reference missions: a year-long mission to ISS; a month-long mission to the moon; and a 30 month mission to Mars. The first one year mission to the ISS was recently completed. With the operational end of the International Space Station (ISS) in sight, the first test flight of Orion EM-1 behind us, and exploration groups architecting proving ground vehicles Mars focus systems and integration [6], the appropriate time to respond more fully to the vision of Safe Passage is now.

Recommendation 2 in Safe Passage called for NASA to develop a comprehensive health care program for astronauts that will allow NASA to collect and analyze data necessary to support human spaceflight. Achieving this goal requires the integration of exercise and performance information as well as environmental monitoring into the crew health system. Integration of health information into the larger health system over time normalizes the data collection and handling needs for future systems. Recommendation 4 from Safe Passage also highlighted the need for behavioral health and other system monitoring and integration with the larger medical system.

NASA responded to Safe Passage Recommendation 5 with the Lifetime Surveillance of Astronaut Health (LSAH) [7] Program and the formalization of occupational surveillance through a thorough occupational health model that collects and analyses a range of pertinent medical information. This occupational surveillance system provides much of the evidence base for improving our understanding of space related medical events as well as a contextual understanding of research data from other areas including the Life Sciences Data Archive (LSDA) [8]. The LSDA is a database that includes evidence base records from spaceflight missions, analogs, and epidemiology from terrestrial medicine. As we enter the age of genomics and personalized medicine, the centralization and enrichment of data for more comprehensive analysis will present an ongoing challenge.

Technology has significantly changed and evolved since the the ISS was designed, driving advances in medicine and in data systems. Computing power—following Moore's law—has grown exponentially smaller and more powerful, reducing the mass, volume, and power required to enable substantial

processing capability that was not imaginable when construction on the ISS began in 1998. These same advances have profoundly affected the delivery of medical care and communication in terrestrial settings, as they have in space. Understanding and designing flight medical systems to accommodate current information processing standards, and anticipate future capabilities, is critical to enabling sufficient medical capability to support a Mars mission.

II. APPROACH

ExMC leverages the history of early spaceflight medical systems and current ISS operations to design future systems. The progression to greater medical capability as well as more robust data management is apparent over the course of the US space program. In Mercury and Gemini, the medical system consisted of select medications and biomonitoring of electrocardiograph, blood pressure, respiratory rate, galvanic skin resistance, and rectal temperature. These measures were monitored by physicians on the ground. In Apollo, separate medical kits, consisting primarily of medications and bandages, were provided for the command and lunar modules. Skylab carried an enhanced medication formulary, resources to support some expanded medical capability, and crew with 80 hours of paramedic-level training. For Space Shuttle, there were several medical kit sub-packs supplied. These progressive changes eventually led to today's ISS Crew Health Care System (CHeCS). CHeCS is comprised of three subsystems: Countermeasures System (CMS), Environmental Health System (EHS), and Health Maintenance System (HMS). CHeCS includes monitoring for performance and environment as well as medical support for routine medical needs and basic and advanced life support for a crew of three up to 180 days [9].

A human mission to Mars is a challenge outside the bounds of human experience, but within the grasp of our technology and imagination. It is critical to both draw lessons from prior spaceflight experience and to recognize the limits of that experience. Relying too heavily on prior spaceflight experience creates a risk of not challenging assumptions inapplicable to planetary exploration. Each of the earlier medical systems was developed for a close-proximity earth-centred mission that enjoyed the advantages of real-time telemedical support, consumable resupply, and medical evacuation when necessary. Operating outside LEO, without access to these advantages, requires a closer alignment between vehicle engineering and development and medical system development. Success in a human Mars mission begins with two key drivers:

- A comprehensive astronaut healthcare system that is mission-enabling
- A concept of operations that explains how such a system will be implemented in an exploration mission.

All other design, requirements, and research questions will be driven by these two goals. They form the conceptual cornerstone that defines not only the system design but also the supporting research pathway. Using operational stakeholders to identify requirements for an exploration medical system, an applied research program identifies gaps in planned operational medical capability and pursues enabling research and technology development. Using this framework, ExMC works to:

- Identify envisioned medical needs for a human Mars mission.
- Identify operational barriers to meeting those needs.
- Identify key questions the operational barriers raise for meeting medical needs (Capability Gaps).
- Identify applied research goals from the key questions.
- Implement the research pathway recognizing agency requirements and stakeholder interests.

Operational requirements for human spaceflight are documented in NASA Standard 3001[10]. NASA Standard 3001 provides the baseline requirements necessary to initiate design of an exploration class medical system. For instance, it requires some level of crew medical autonomy be designed into a Mars planetary mission. Crew medical autonomy means providing the necessary skills and resources to enable a desired level of medical capability and flexibility without real time terrestrial support. The prior models of planning for medical care relied extensively on subject matter expertise to weigh the risks and benefits of medical capabilities targeted to the flight constraints of the vehicle and mission. For Mars missions, in order to balance the risks of under-providing (increased medical risk) and over-planning (increased mission risk) the medical capability must be viewed as a system within the vehicle so that it can be designed in parallel with the vehicle needs.

III. METHODS

Defining a Concept of Operations (ConOps) is a critical part of medical system design. Developing a viable ConOps requires two key steps. First, core content must be identified, and system needs derived

from that content. Operational medical capabilities must then be pursued or rejected based on their ability to reduce risk and the engineering limitations of the expected vehicle and mission. Second, programmatic realities, such as schedule and budget, must be addressed to enable system acceptance and support.

Core Content for Exploration Medicine

Concept of Operations for Exploration Medicine

The ExMC ConOps captures the planned operational use of the exploration medical system. Specifically, the ConOps provides guidance on medical capabilities required for prevention, diagnosis, treatment, and rehabilitation as envisioned for a Mars Mission to enable crew medical autonomy. Critical for Mars exploration, individuals will need to be sufficiently trained as medical officers, and the exploration medical system must be operable at the skill level of those selected to serve as medical officers.

The ConOps also envisions and documents both planned and unplanned medical activities so that capabilities required enable those activities can be identified. This in turn allows ExMC to derive the functional requirements and concomitant system development and research opportunities. In areas where there is uncertainty, the ConOps aids in the identification of gaps that guide the research pathways for either an enhanced evidence base or technical development.

Risk Assessment Tools and Trade Space

Judicious investments in research capability and system design require a quantitative language that is understood and agreed upon by both medical and engineering personnel designing a given system [5]. The ability to quantitatively trade in the medical risk space is a pre-requisite for making informed decisions about the impact on mission medical risk of including or excluding specific medical capabilities. It is also a pre-requisite for demonstrating the effects of vehicle mass and volume trades on the medical risk posture in mission planning.

Planning for unknown medical events presents a significant challenge. Planning and research require a metric for medical risk that is measurable in order to demonstrate value. The current system of likelihood vs. consequence is limited in the face of medical needs because the space of all possible medical issues is untenable to list and estimate on evidence-based likelihood. As a result, ExMC uses a strategically

chosen subset of conditions to provide a manageable approach to likelihood.

Consequence provides a means of assessing the expected effectiveness of a medical capability in mitigating the effects of a medical condition occurring. It is impossible to predict the effectiveness of all possible medical treatments given an assumed resource set. It is possible, however, to measure a proposed resource set against a defined standard of best practice, or a gold standard. If the gold standard resource set is defined as resources available to a U.S.-based tertiary care hospital, then the preventive, diagnostic, treatment, and rehabilitation capabilities of a proposed medical system can be measured against that gold standard. This comparison provides a measure of *medical readiness* rather than predictable effectiveness. Since even the relatively unlimited capability of a tertiary care hospital cannot provide perfect outcomes, medical readiness as measured by capability provision is a viable risk metric.

Once quantitative measurements of likelihood and medical readiness (as a proxy for consequence) are developed, there is value in a modelling approach to augment subject matter expert evaluation of these complex questions in the medical/engineering domain. Probabilistic Risk Analysis (PRA) in the event space and a relational database approach to the medical call space are discussed here and elsewhere in more detail [11].

Medical Data Architecture

Human Mars missions will be severely resource limited and the medical system will be reliant on sound engineering design. Integration of the CMS and EHS systems into the medical system of the ISS demonstrate a recognition that the medical system, vehicle, and the larger human health and performance needs (e.g. nutrition and exercise) are closely tied. All of these systems require the handling of significant amounts of information. Data from medical monitoring devices must be intelligently combined with other monitors (environmental, performance, etc.) and designed into the vehicle informatics system. This system must be able to not only collect and process data, but also synthesize large amounts of information and present it in such a way that the information delivered to crew is succinct and relevant. A Medical Data Architecture (MDA) is a core need given the massive amounts of information and potential for cognitive overload of crew who must be able to interpret information and act autonomously.

Knowledge support tools are ubiquitous in terrestrial medicine, and augment and refresh medical knowledge of physicians practicing on the Earth. Terrestrial medicine also has the benefit of immediate access to ‘Just in Time’ training videos for medical procedures of limited complexity. Designing to at least the level of complexity and information processing that is exhibited by most current smartphones on earth is a minimum step beyond the limitations of the system in place on the ISS. Centralizing medically relevant information, interfacing with vehicle systems, managing medical devices, and providing mirrored information through telemetry to mission flight surgeons are all necessary functions of an MDA for a human Mars mission.

Medical System Appliance Development

Medical System Appliance development is a critical part of the ExMC research pathway that naturally flows from the MDA. ExMC’s ConOps and risk assessment define the medical appliances desirable for an exploration medical system. Many medical technologies will continue to mature through earth-based markets. It is likely, however, that terrestrial technology will have deficiencies in terms of mass, volume, power, and system interfaces that will need to be addressed through technology development processes. Command and control of medical devices (such as ultrasound which is currently used on ISS) should be seamless with the shipboard computers as should the transfer and storage of medically relevant information such as images, device outputs, physician notes, monitoring data, and consumables tracking.

Ethical Framework

Properly assessing research and design requirements for exploration medical capabilities requires a new ethical framework for the delivery of care. The Institute of Medicine (IOM) found that the “only ethically acceptable” option was for NASA to provide exceptions to existing standards rather than relaxing standards or creating new standards [12]. As a result, the ethical framework for exploration will need to balance the overall risk of the mission, resource constraints, and NASA’s obligation to provide the greatest protection practicable for crew. This balance will require the element to clearly identify trade space in which medical capabilities will be prioritized: in a mass and resource constrained environment, the decision to include one capability will force exclusion of other capabilities. Further, mission limitations, such as communication delays and the inability to return a sick or injured crew member to Earth may require real time decisions that balance individual care with

mission success and broader crew survival. The ethical framework, paired with a robust medical risk model, should inform these trades. The Element will document significant prioritization decisions; provide assumptions, context, and rationale for those prioritizations; and seek guidance from the NASA Health and Medical Technical Authority (HMTA) and bioethicist as appropriate.

Decision Framework

Level 1: As a general rule, should NASA conduct space missions that will (a) fail to meet health standards, (b) involve significant risks where there are no applicable standards, and/or (c) involve such great uncertainty that NASA cannot exclude the possibility of a or b? If so, what criteria should be used to determine whether exceptions for specific missions should be allowed?

Level 2: Given authorization for missions that will likely fail to meet existing health standards, is a specific long duration and/or exploration mission ethically acceptable?

Level 3: What factors should be considered as NASA and individual astronauts make informed decisions about crew selection and individual astronaut participation for a given mission?

Figure 2 Ethical Decision Framework proposed by the IOM report titled Health Standards for Long Duration and Exploration Spaceflight Ethics Principles, Responsibilities, and Decision Framework, [12].

In addition to clarifying the ethical trade space for medical decisions, NASA will also need to address the statutory and regulatory framework for the collection and use of genetic information. Personalized medicine and pharmacy will be a significant component of an effective exploration medical capability. This capability cannot be developed without access to genetic information on crew. Currently, the Genetic Information Nondisclosure Act (GINA) [13] allows for the use of genetic information to develop countermeasures for hazards, but there are some potential impediments to the collection of data, and NASA needs to ensure that sufficient protections are in place to prevent the misuse of genetic information in prohibited areas such as selection and assignment.

NASA may wish to consider treating all early planetary missions as experimental, rather than operational [14]. Thus, the crew participating in them could be asked to provide an informed consent to those risks that exceed the normal operational boundaries that have enveloped human flight in LEO. The IOM characterized this as ensuring that the crews “exercise voluntariness” [12] For the crew to provide a valid consent, each individual would need to be presented with an individualized risk portrait, based on the best available information about the predicted impact of the space environment on his or her short and long-term health. These risk portraits would contain significant uncertainties. The informed consent would also need to delineate the perceived scientific and societal value of the mission, allowing the individual crew member to balance risks and benefits [12].

Finally, in addition to individual risk, NASA must assess whether overall mission risk is ethically acceptable. This ethical inquiry will focus on the societal benefit of the mission, its urgency, the presence of a robust informed consent process for the crew, and a commitment to mitigating unavoidable harms through the provision of long-term health care and surveillance [12].

Programmatic Imperatives

To enable a useful system scope and research pathway, the programmatic needs within the agency must be addressed in addition to the technical content. The following programmatic needs are critical:

Identify a clear delivery target. In order to properly scope the system and provide a timeline against which to measure potential research investments and included or excluded capabilities a realistic schedule is required. Given the limited resources available, a schedule constraint is critical to focus and direct an applied research program.

Identify and create ongoing communication pathways with stakeholders. Early identification of stakeholders is required. Forward planning to ensure appropriate system interface with a future vehicle requires open communication pathways with future exploration architectural teams as well as engineering teams that are responsible for vehicle subsystems. Creation of a ConOps and Risk Analysis tools must reflect operational medical experience and crew experience of spaceflight needs.

Revise the research pathway as necessary. The applied research program pathway for exploration as implemented by ExMC must focus on research that ultimately informs and supports medical operations in an exploration mission. Prior to this redesign the ExMC focus for research was on single-point solutions for individual medical issues. These solutions were not contextualized or given relative prioritization in the context of expected operational need. In February of 2014, the Element started this restructuring process to approach exploration medical needs from a holistic and integrated standpoint. In this approach, research gaps are identified from Core Content above. Any research lines that do not address expected medical system needs should be terminated to accommodate operationally relevant questions.

Create a means for continuous evaluation of element products. An exploration medical system must be evaluated from the standpoint of its capacity to provide

clinical medical capability and collect data to inform an ongoing occupational health model. Clinically current medical practitioners are the best judge of endpoint clinical utility. As a result, ExMC stood up the Clinician's Group composed of aerospace experienced medical personnel to help guide, assess, and develop the ConOps, inform Risk modelling, and evaluate research products and system development in terms of their clinical utility. This group includes representation from Physicians, Nursing, and Pharmacy disciplines.

Create a means for systematically identifying and managing system interfaces. The inherent complexity of an information management system that interfaces with a vehicle as well as multiple subsystems required to support exploration medical care dictates a highly structured, systematic, and disciplined approach. The ExMC Systems Engineering and Integration (SE&I) Group is tasked with identifying and negotiating with stakeholders and identifying and managing system interfaces for the Exploration Medical System development. Needs identified by the SE&I group also help prioritize research investments designed to increase medical capability and to reduce medical risk while minimizing impact to the mission and vehicle.

IV. CURRENT STATUS

Core Content Status

ConOps development starts with the mission of interest, a Mars mission, and breaks the mission into phases. First is the Transit Phase to and from Mars which identifies system needs for the transfer vehicle. Second is the Planetary Phase which identifies system needs for the planetary habitat. Both of these phases have an identified sub-phase titled Extravehicular Activity (EVA). EVA activity changes the medical risk profile depending on frequency and expected exposures. Each of these phases is further divided into functional domains for medicine: planned medical events and unplanned medical events. Planned medical events allow for decomposition into crew Self-Directed Care, Crew Medical Officer-Directed Care, and Emergency Care domains.

The breakdown in these categories are dictated by two principles: 1) respect for crew autonomy in symptomatic development (crew members can identify and manage small problems and ask for CMO assistance when uncertain); and, 2) time available for consultation as dependent on a condition and its severity (i.e., trauma and bleeding may require care and stabilization prior obtaining guidance on management from Earth).

The role of ground support in the Exploration paradigm is in development. The current approach utilizes a store-and-forward type consultant role for earth-based medical support with a system need to supply mirrored medical information to earth medical support in a near-real-time paradigm.

Medical risk assessment tools have been in development for a decade at NASA. The best evidence-based model to date is the Integrated Medical Model (IMM). The IMM provides a means of merging the spaceflight and terrestrial medicine evidence bases with Monte Carlo simulation to estimate the probability and likelihood of unplanned medical conditions [15]. This projection of what medical events are likely to occur allows the development of baseline needs estimates. The IMM holds assumptions including event type, frequency, and resource utilization that are tied to prior human spaceflight experience and medical practice. It is critical to recognize the model limitations and the model output must be interpreted by subject matter experts.

In addition to the IMM, the Medical Optimization Network for Space Telemedicine Resources (MONSTR) allows trade space analysis for resources needed to implement capabilities in the ConOps. This takes the form of a capability 'wish list' that a terrestrial physician might have. This allows deconstruction of unplanned medical needs, starting with the Exploration Medical Condition List (EMCL) [16]. Deconstruction of the medical capabilities desired in the ConOps starts with medical condition in the best case or worse case scenario, medical capability needed to diagnose or treat, actions required by the capability, and finally resources required to implement the action. This allows relational mapping of resources common to many conditions to be prioritized above rarely used resources; it also allows understanding of the impact of inclusion or exclusion of specific resources or decisions not to treat on the mass, volume, power, and capabilities domains that a system entertains. The prototype version of the MONSTR tool had information populated by six board certified physicians in Aerospace Medicine, Emergency Medicine, Family Medicine, Internal Medicine, and Physical Medicine and Rehabilitation. Early MONSTR analysis identified the provision of a safe and effective pharmacy as the highest priority; this was captured in the research pathway as MEDO2 Pharmacy Gap.

The Medical Data Architecture project was initiated prior to the completion of the ConOps documents because of the long lead-time required to create a

relevant software architecture that could provide a framework for the information management required from the medical system appliances and human and environmental monitoring data that is anticipated prior to a detailed ConOps delivery. The relevant focus for the initial MDA test bed was drawn from Medical Narratives written by the Element Scientist. Provision of a first test bed for evaluation by the Clinician's Group and SE&I Team includes software architecture, electronic health records, electrocardiogram, software for pharmaceutical reconciliation and research tracking, and a prototype biomonitoring system developed by the Canadian Space Agency.

This is also the starting point for Medical Appliance needs. Though the ConOps will drive which medical appliances are given highest priority, an early need for the MDA system is testing the ability to interface with a variety of appliances. This helps elucidate engineering and software challenges early in the process. An Increment and Iterate approach to the development of the MDA/Medical Appliance system is planned with roughly yearly deliveries for evaluation and feedback that increment the level of capability the system supports.

Early test bed evaluation allows opportunities to identify software and interface challenges early in the design cycle. Conducting these early tests will also help to identify future needs for testing and verification and validation that requires continuous SE&I involvement and oversight. As the system matures, testing in more challenging analog environments is anticipated to stress the system and identify needed modifications as early as possible through usage and human factors evaluation. This approach responds to Safe Passage Recommendation 3: *"using more extensively analog environments that already exist and that have yet to be developed."* [4]. An initial requirement of the project is to provide the capability to maximally accept the relevant data and command and control interfaces available to optimize the ability to draw on Commercial off the Shelf (COTS) technologies as they mature through terrestrial market utilization.

Finally, the Ethics Pathway is assigned a formal gap in the ExMC research structure described below, MED06. Populating the Gap requires more maturity of understanding of the system limitations; as a result, there is no assigned content at this time. Content will be assigned as the ConOps development dictates a need for answers to operationally challenging questions and as system-vehicle integration more closely identifies the true impact of resource limitations on the provision of medical capability.

Current Exploration Medical System Status

The ExMC element is working toward delivery of a system for flight testing to the proving ground vehicle in 2025 [6]. The proving ground vehicle is a lunar orbit testing platform intended to test and demonstrate the capabilities required for a Mars Mission. ExMC chose the proving ground vehicle as its target because the architecture of the vehicle is sufficiently immature to allow delivery of requirements for a medical system that can influence vehicle design. ExMC intentionally skipped the Orion vehicle because it is so far along in its flight pathway that it is impossible to influence central planning from a medical needs standpoint.

The proving grounds vehicle target also helps identify early stakeholders within NASA and outside of NASA among the international partners who are likely to have a role in bringing forth an exploration medical system. Within NASA, these stakeholders include the Space Medicine Operations Division, HRP, HSRB, the Office of the Chief Medical Officer, and the Engineering groups responsible for flight designs and hardware such as ECLSS and Avionics. Stakeholder identification and communication is a continuous process, and stakeholders amongst the international partners include the Canadian Space Agency. Others have yet to be identified.

In late 2015, HRP Management reprioritized the ExMC research pathway to meet the Core Content needs [2]. The first three core content areas discussed above form the basis from which all other research needs are derived. ConOps development, Quantitative Risk Analysis, and MDA have assigned Gap numbers within the ExMC research pathway indicating the need to create content and define deliverables. The content areas are assigned MED01, MED08, and MED07 respectively. Medical Appliances and Ethics are assigned MED13 and MED06 respectively. The numbering is consistent with an organizational strategy rather than intellectual primacy. Given the conceptual drivers described above, ExMC research products fall into one of three categories: operations research, information resources, and technology development. This trilogy of research product identification and development is modelled after the Department of Defence Architecture Framework (DODAF) approach [17]. Figure 3 shows these categories with focus within the circles and high-level interfaces between the domains.



Figure 3. Relationships between research divisions in the Exploration Medical Capability Element.

Figure 3: ExMC Research Pathway breakdown structure by research category with influences shown here.

ExMC research pathway restructuring used the core content needs identified above to identify gaps in medical capability to support the creation of the exploration medical system. The gaps were numerically ordered according to research domain (Fig. 4). Figure 4 lists the Gaps with the breakdown of research domains mapped to the corresponding relationship and color found in Figure 3.

Med01	We do not have a concept of operations for medical care during exploration missions.
Med02	We do not have the capability to provide a safe and effective pharmacy for exploration missions.
Med03	We do not know how we are going to apply personalized medicine to reduce health risk for a selected crew.
Med04	We do not have a defined rehabilitation capability for injured or de-conditioned crew members during exploration missions.
Med05	We do not know how to train crew for medical decision making or to perform diagnostic and therapeutic medical procedures to enable extended mission or autonomous operations.
Med06	We do not know how to define medical planning or operational needs for ethical issues that may arise during exploration missions.
Med07	We do not have the capability to comprehensively process medically-relevant information to support medical operations during exploration missions.
Med08	We do not have quantified knowledge bases and modeling to estimate medical risk incurred on exploration missions.
Med09	We do not have the capability to predict estimated medical risk posture during exploration missions based on current crew health and resources.
Med10	We do not have the capability to provide computed medical decision support during exploration missions.
Med11	We do not have the capability to minimize medical system resource utilization during exploration missions.
Med12	We do not have the capability to mitigate select medical conditions.
Med13	We do not have the capability to implement medical resources that enhance operational innovation for medical needs.

Figure 4: ExMC Research Pathway Gaps. Gaps 01-06 fall into the Operational Research Domain, Gaps 07-10 fall into the Information Resources Domain, and Gaps 11-13 fall into the Technology Development Domain.

Functionally, these gaps proceed from the ConOps and Risk assessment, to prioritize medical capabilities to the information resources and technology development domains, to products needed to test and evaluate an operationally relevant system. Each of the Gaps in this research pathway either influences or is influenced by the progress in other Gaps. This requires definition of deliverables from intellectually early Gaps to following Gaps. For example, the medical capabilities identified by the ConOps (MED01) implies content for a Training Gap (MED05) that must be delivered and handled by the MDA (MED07). The content development in the Training Gap (MED05) focuses on the following questions: What medical training is required and what conditions should it address? How do we provide training for those skill sets and retention of skills over the long mission

duration? How is that training provided by the medical system to the crew? Another example is the influence of the ConOps (MED01) on the Pharmacy Gap (MED02): what conditions we plan to provide treatment for defines what medications are prioritized in the provision of a safe and effective pharmacy for crews. Those results then form a starting place for understanding which medications are likely to be safe and effective throughout the mission and which are not. Those that are prioritized high but are likely to be unstable, drive research goals on true shelf life, alternatives, or in-mission synthesis options.

V. CONCLUSIONS/ FUTURE WORK

The medical challenges expected in a human Mars mission are unlike anything we have experienced in prior human spaceflight. Provision of medical care in the face of an inability to resupply materials, inability to evaluate sick or injured crewmembers, and the loss of real-time telemedical support requires a paradigm shift in the planning and research approaches. This work documents the conceptual drivers required to reduce medical risk in a Mars exploration mission.

- A paradigm shift in medical planning is required to meet the needs of a Mars mission.
- Vehicle integration of a medical system is a requirement of human-centric mission planning.
- A target program/vehicle enables schedule creation and acts as a driver for an applied research program.
- Quantitative and modelling approaches to medical risk characterization should supplement subject matter expert opinions as a basis for informed decision making.
- Sequential approach to research program gap development driven by a Concept of Operations is critical to program relevancy.
- Continuous evaluation by clinicians of product utility can minimize extraneous research expenditures.
- A systematic and disciplined Systems Engineering and Integration approach is the cornerstone of medical system development and vehicle integration.

These challenges were enumerated and a vision proposed in Safe Passage fifteen years ago. Now with the retirement of the ISS approaching and the first unmanned flight of the Orion vehicle behind us, we are at a point where the transition to a human-centric mission architecture must start to become a reality if exploration missions are to succeed. Medical system requirements and vehicle design must share

dependence to minimize the risks to crews. This transition has started but is not yet complete. It coexists with a need to cooperate with and share responsibility for medical priorities of international partners as mission designs continue to mature.

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