TOPICAL:

Development of Medical Capabilities and Technologies for Health Monitoring, Diagnostics, and Treatment during Human Exploration Spaceflight



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Introduction

Deep space exploration missions to the Moon and ultimately Mars will present unprecedented challenges for supporting astronaut health and performance. "[The] assumption [heretofore] has been that risk of vehicle system malfunction far outweighs the risk of human system failure... [Therefore], NASA buys down the risk of failure of the human system through rigorous selection of individuals designed to minimize medical issues and optimize available capability in flight" (1). Justifiably, medical conditions have not been a primary driver of risk in the last half-century of human spaceflight experience conducted primarily within the confines of low Earth orbit (LEO).

However, deep space exploration poses orders of magnitude more significant design and operational challenges of medical systems and includes the acknowledged spaceflight hazard of "Distance from Earth" (2). The Moon is approximately 1,000x farther from Earth than LEO, and Mars is, on average, 560x farther away still. Such distances create multiple medical system constraints wherein communication delays (up to 24 minutes one way for a Mars mission) will require an unprecedented degree of crew autonomy as substantial lag times in data transmission and bandwidth limitations will further limit reliance on ground support (3).

Resupply of consumables will be extremely limited or non-existent. As a result, medical system designs need to provide broad capabilities while anticipating numerous contingencies. For example, crew member evacuation will not be possible given extended transit times (Mars: 6 to 9 months) and planetary alignment limitations (4). Further, typical engineering and mission resource limitations (considerations of mass, volume, and power where enormous kinetic energies are needed to escape Earth's gravity and achieve Mars orbit) will be even more restrictive given the significant demands and functionalities required of future exploration systems. Notably, such restrictions will increase demand on the extent and depth needed of crew members' knowledge, skills, and abilities (KSAs) and the medical system's capacity to support real-time decision-making therein.

Accordingly, transformative solutions are needed to provide future space travelers health monitoring, diagnostic, and treatment technologies that are: (a) multi- and cross-functional ("dualuse" and supportive of clinical and research needs, simultaneously); (b) non-invasive/contactless (less limited by monitoring conditions); (c) vehicle or habitat-integrated (supporting optimal exchange/utilization of crew health, performance, and vehicle/habitat data necessary for prediction, detection, analysis, and intervention in medical conditions in a progressively Earth-independent fashion); and, (d) require minimal expenditures in mass, volume, power, and data. To that end, this paper describes the key areas and critical gaps being addressed by NASA's Human Research Program (HRP), Systems Capability Leadership Team (SCLT), and its Biological and Physical Sciences (BPS) Division, as well as how future collaborations and technologies are needed to develop the capabilities required for robust future "exploration-forward" medical systems.

Integrated Data Architecture

An integrated information architecture system focused on crew health and performance data is critical in reducing uncertainty around what information is needed to aid crew autonomy for future exploration missions. NASA is developing the Crew Health and Performance – Integrated Data Architecture (CHP-IDA) system as a platform to enable the amalgamation of a variety of crew-relevant data sources and applications. Candidate data includes medical diagnostic, vehicle, and

environmental data (ambient CO₂ concentration, radiation, acoustic levels, microbial/chemical concentrations) germane to crew health and well-being. Advanced analytics allow for integrating and operationalizing "all-source" data, driving decision support tools supportive of progressive autonomy. CHP-IDA is expected to yield new and cohesive insights into the impact of multiple, intertwined parameters on the health and performance state of the crew. In addition, CHP-IDA directly supports automated clinical decision-making capabilities, thereby reducing overall reliance on ground systems for primary guidance. NASA considers the development of an integrated data architecture system to be a critical step in reducing the risk of adverse outcomes and performance decrements from medical conditions in spaceflight (5).

Electronic Health Record (EHR)- Currently, the EHR is accessible only by Flight Surgeons in Mission Control and physicians in the NASA Johnson Space Center Flight Medicine Clinic. Ground personnel must manually enter medical data or information obtained from crew via Private Medical Conferences (PMCs) into an EHR currently unavailable to crew members. An access-controlled, Protected Health Information (PHI) compliant EHR would need to be accessible by ground-based Flight Surgeons, NASA physicians, and the Crew Medical Officer for exploration missions. Relevant data and notes would be captured or entered into the EHR then synchronized within the CDSS and ground-based systems. In addition, the EHR would be interoperable between spacecraft and accompanying crew support systems (such as the transit vehicle, rover, and, as well, the surface habitat module) to ensure crew health information is integrated and available across all mission platforms. Notably, a comprehensive and cross-platform EHR has not been developed for nor deployed in the space environment to date.

Medical Inventory Tracking- Exploration class missions will need an automated system to track medical consumables and equipment. Such a system would need to operate as efficiently as possible, ideally in real-time as resources are expended, thereby decreasing the need for crew or the ground team to maintain a "hand count" inventory. Stand-alone or combination "low-" or "no-contact" tracking technologies would complement the crews' ability to manually input decrement or restock information or specify alternative storage locations. For example, pharmaceutical tracking would provide actual- or near-real-time inventories of available medications, amounts, and expiration dates. In addition, the pharmaceutical "inventory" should provide suggested, FDA or EU compliant "Medication Guidelines" with anticipated effects and available alternatives. All of this information would be accessible both to ground teams (Flight Surgeons, bio-medical engineers, pharmacy) and the crew via an EHR interface coupled to an integrated vehicle data/inventory system, synchronized through the onboard CHP-IDA with access made available through the clinical decision support system (CDSS) user interface.

Clinical Decision Support System (CDSS)

A comprehensive, on-board CDSS will help astronauts assess and diagnose conditions, determine appropriate responses, and guide the provision of tailored and evidence-based treatments based, in part, on current and historical medical data, available diagnostic equipment and supplies (e.g., medical consumables), and vehicle/environmental health parameters while considering contextual factors and mission constraints. Additionally, in anticipation of an incapacitated Crew Medical Officer (CMO) scenario, the CDSS must provide the capability to train a non-medical member in complex medical emergencies while additionally providing the capability of augmenting either CMO or non-medical expert skillsets where delayed or absent communication with flight surgeons

is encountered. Accordingly, the CDSS must enable complex inputs involving health, wellness, task performance, environmental, and vehicle domains to inform risk and empower the crew's decision-making capabilities. Such a system is necessary to address challenges in developing and exploiting a self-contained medical system that enables health care without assistance from Earth.

Software-Based Diagnostic and Treatment Aids- With increasing crew autonomy required during exploration missions, software-based diagnostic and treatment aides are needed to guide a Crew Medical Officer (CMO) or other crewmembers through medical diagnostic and treatment processes. An optimal, integrated software system would provide an early set of "differential diagnoses" and associated "follow on questions/prompts" (lab or imaging tests to consider) based upon collected signals derived from crew member behavior patterns, captured vital signs, symptoms, exam findings, and environmental cues. In addition, a CDSS (initially referenced to evidence-based terrestrial and LEO spaceflight data) would assist in determining the highest probability conditions, treatments, and outcomes, augmented by Earth-based expert guidance when bi-directional communications become available.

Just-in-Time Procedural Training and Real-Time Guidance- Crews will receive medical training before launch but providing all crewmembers with the skills necessary to account for all possible medical conditions is impossible. In addition, long-duration missions will incur the real risk of medical procedure skill degradation. Just-In-Time (JIT) training may fill this critical gap. JIT would include a suite of multi-modality resources (audio/visual/tactile feedback, virtual/augmented reality) that would lead astronauts through the steps of complex medical procedures and provide baseline knowledge (physiology, anatomy, and technique) via access to CDSS stored "on-demand" information. Identified critical capability gaps include understanding the extent and frequency of required refresher training, appropriate applications of technologies that improve JIT and real-time guidance measures, and domain-specific KSA retention over time.

On-board Computational Capabilities to Enable Artificial Intelligence (AI) and Machine Learning (ML) Algorithms- All current AI/ML devices used for rapid analytics interpret longitudinal medical data by accessing large databases and computer clusters, giving the impression of immediate diagnostic capability. Deep space communication and on-board system resource challenges will impose necessary limits on previously terrestrially based and supported functionalities. The development of more efficient AI/ML algorithms (nominally to reduce computational burdens and mass/weight requirements while simultaneously improving capability) will be essential to support deep space missions in the coming decades. An example of this schema is NASA's partnering with industry to develop novel space biology-centered algorithms.

Medical Diagnostics

Advanced medical diagnostics will be required to support and ensure successful future deep space exploration missions. The ability of both crew and ground-based medical support personnel to detect, assess, and treat medical conditions (and, preferably, prevent them) will depend on technologists, mission planners, and spaceflight crew to anticipate, monitor, and adapt to physiologic and behavioral variations. The tools required to meet these challenges may include advanced multiplexed imaging modalities, automated clinical laboratory devices, and multifunctional medical diagnostic/treatment devices integrated with non-intrusive/non-contact-based physiological (e.g., vital signs) monitoring systems (6), all feeding into a centralized information data system displaying robust clinical decision support paradigm outputs.

Imaging- Medical imaging is an essential diagnostic capability for a spacecraft medical system. Examples of imaging technologies include handheld portable ultrasound devices, miniaturized radiographic systems, digital ocular (Optical Coherence Tomography, fundoscopy), and otoscopy imaging devices. Unfortunately, many of these technologies do not yet exist or fit within the resource constraints of a nominal exploration spacecraft design. Enhanced imaging analysis systems integrated into a CDSS will permit the crew to make more efficient, time-critical, and clinically relevant decisions in close time proximity to image acquisition and processing, with outputs stored in an Electronic Health Record (EHR). This process allows independent analysis and decision support backed up by post hoc confirmation when communication with ground support systems becomes available.

Laboratory Studies- Current laboratory analysis capabilities in LEO are extremely limited and do not include routine tests widely available to clinicians on Earth. Human laboratory data is currently derived from on-orbit collected samples returned to Earth for analysis. In-situ, "point of care" modalities, including standard lab tests (complete blood count, metabolic and body fluid analysis), performed on spaceflight compatible specific hardware and platforms, must advance significantly to meet future needs. Verifying diagnostic utility in an environment lacking gravity, in the presence of space radiation, and enclosed environments poses significant technological challenges. Minimal mass, volume, consumables, and reagents - with components that last the duration of exploration missions (up to three years) - are essential. Seamless, integrated medical device data must interface with and be available through planned vehicle data architectures.

Multifunctional Medical Diagnostic and Treatment Devices- Combined, multifunction diagnostic modalities reduce a future medical system's mass/volume/power footprint and allow for delivering integrated clinical capabilities. For example, state-of-the-art next-generation medical devices combine baseline technologies such as electrocardiogram, defibrillation, digital laryngoscopy, ultrasound, vital signs monitoring, and telemedicine video capability within a single system. In addition, future medical systems' footprint, portability, and interoperability across different mission components (e.g., spacecraft, surface habitat, rover) may be further optimized by combining multiple capabilities into consolidated low-profile form factors.

Vital Signs and other Non-Intrusive Monitoring- Vital sign monitoring is essential for any future long-duration mission spacecraft medical system. This includes the traditional need to obtain vital signs for unplanned medical events or contingencies and the broader need for routine monitoring that can inform algorithms for early detection of illnesses (such as infection) where identifying sub-clinical or subtle findings is challenging even for trained medical professionals. Ideally, novel, unobtrusive (e.g., narrowband radar or video-processing) technologies will allow regular, contactless monitoring with resulting data being processed and integrated with other health and performance parameters within the CHP-IDA and CDSS.

Behavioral Health and Performance

Exploration missions will include physical and psychosocial stressors, including isolation, confinement, interpersonal issues with fellow crew members, and family illnesses/incidents or major events back on Earth. Behavioral health and performance (BHP) is currently optimized through crew selection and support provided in real-time by BHP ground providers. In addition, astronauts have regularly scheduled private psychological conferences while participating in LEO missions. However, the communication delays anticipated during a Mars mission will notably

impact real-time discussion and intervention. Therefore, there is an increased need for semi-autonomous BHP operational solutions such as psychological diagnostic and treatment support aides and autonomous psychotherapy modalities. Such solutions – providing opportunities for early and Earth-independent intervention – may derive from or be supplemented by non-invasive and contactless means of identifying issues in a crewmember's mood or crew cohesiveness, thus preventing significant problems that could negatively affect crew health and performance, and ultimately mission success. Advances in our overall understanding of the interplay between human physiology and behavior, as affected by spaceflight-related factors, will guide the development of more robust solutions and methodologies that optimize crew well-being and effectiveness.

Pharmacy

Providing a safe and effective pharmacy is a critical component of any exploration medical system. Indeed, pharmaceutical products are expected to be among the most substantial and vital components within an exploration medical system (7) and the focus of significant challenges. First, resupply will likely prove impossible, and mission durations will last beyond expected medication shelf lives. Second, deep space travel will expose pharmaceuticals to galactic cosmic radiation and repackaging of drugs may lead to component degradation due to ambient or elevated CO₂ exposure. Finally, the astronauts' physiology will change over time, leading to potential pharmacokinetic/pharmacodynamic (PK/PD) perturbations (8). A better understanding of such perturbations in physiology and improved drug packaging options (that attenuate degradation) will be needed to address such challenges. Point of care analysis to measure active pharmaceutical ingredients (API) and toxic degradation products could support alternative dosing regimens. Futuristic solutions include combining knowledge of space-related degradation pathways with novel, on-demand ("common stock") space-based, reduced up-mass drug manufacture capability.

Conclusion

Increasing distance from Earth will require more independent, crew-centered decision-making and increased reliance on before and in-mission training supported by a CDSS. Accordingly, combining the realms of physical science with the assessment and prediction of human behavior, physiology, and biology - and how these various systems respond to spaceflight - has and will continue to provide valuable feedback driving future spacecraft design input. It is, therefore, incumbent upon future technologists to consider how the function and application of their discoveries merge and share attributes with other systems to achieve a collective set of goals and objectives that enhance overall mission success. In addition, exploration class spaceflight medical care considerations will be subject to new and significant constraints compared to today's LEO paradigm. As a result, supporting astronaut health and performance on these missions will require substantial advancement in medical system capabilities. The next decade must see the development of new monitoring, diagnostic, treatment, and computational technologies supported by analog experimental data intended to fill these critical gaps. A significant challenge will be developing new technologies that elucidate, refine, and integrate large amounts of data from multiple sources among interrelated (and perhaps unrelated yet salient) systems and archetypes. These efforts will hinge upon our learning to more fully translate and integrate knowledge that considers and safeguards astronauts' short and long-term health and wellness while seeking to facilitate our future return and exploration of the Moon, and eventually, to Mars itself.

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