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NASA'S EFFORTS TO MANAGE HEALTH AND HUMAN PERFORMANCE RISKS FOR SPACE EXPLORATION

October 29, 2015

Report No. IG-16-003





Office of Inspector General

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RESULTS IN BRIEF

NASA's Efforts to Manage Health and Human Performance Risks for Space Exploration

NASA Office of Inspector General
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IG-16-003 (A-14-011-00)

WHY WE PERFORMED THIS AUDIT

Space flight is an inherently risky endeavor and NASA has identified 30 human health and performance risks associated with space travel, including Behavioral Health and Performance, Inadequate Food and Nutrition, Space Radiation, and Vision Impairment and Intracranial Pressure. In addition, NASA's current plan to send a crewed mission to the Martian surface by the 2030s will expose astronauts to new and increased hazards. Although the Agency has developed mitigation strategies to reduce the impact of most of the risks associated with travel in low Earth orbit, many of the risks associated with long duration space travel are not fully understood.

To better appreciate the risks to human health and performance associated with space travel, NASA and its partners are performing a variety of studies on Earth and the International Space Station. In addition, multiple NASA offices play a role in developing procedures, medications, devices, and other strategies (countermeasures) to mitigate these risks, including the Human Exploration and Operations Mission Directorate (HEOMD), which provides leadership and management of NASA's human space exploration programs; Human Health and Performance (HHP) Directorate, the Agency's primary resource for human health and performance issues related to space travel; and Human Research Program (HRP), which is focused on investigating and mitigating the highest risks to astronaut health and performance. In 2014, HRP completed a detailed schedule known as the Path to Risk Reduction setting forth the rate by which the Program expects to complete development of countermeasures for various risks through 2028.

In this audit, we examined NASA's efforts to manage the health and human performance risks posed by space exploration. To determine how NASA manages risk mitigation, we reviewed the status of HRP's human health and performance risks based on the Program's schedule and risk matrix. We also reviewed Federal and NASA policies, regulations, and plans, and interviewed representatives from the Office of the Chief Health and Medical Officer, HEOMD, HHP, and HRP; various subject matter experts; and a selection of astronauts.

WHAT WE FOUND

Although NASA continues to improve its process for identifying and managing health and human performance risks associated with space flight, we believe that given the current state of knowledge, the Agency's risk mitigation schedule is optimistic and NASA will not develop countermeasures for many deep space risks until the 2030s, at the earliest. One of the major factors limiting more timely development of countermeasures is uncertainty about the mass, volume, and weight requirements of deep space vehicles and habitats. Moreover, even as NASA gains additional knowledge about its vehicles and habitats and the effects of radiation and other space conditions on the human body, the Agency may be unable to develop countermeasures that will lower the risk to deep space travelers to a level commensurate with NASA standards for low Earth orbit missions. Accordingly, the astronauts chosen to make at least the initial forays into deep space may have to accept a higher level of risk than those who fly International Space Station missions. We also found that NASA cannot accurately report the true costs of developing countermeasures for the identified risks.

Furthermore, NASA's management of crew health risks could benefit from increased efforts to integrate expertise from all related disciplines. While many life science specialists attempt to utilize the range of available expertise both inside and outside the Agency, NASA lacks a clear path for maximizing expertise and data at both the organizational and Agency level. For example, NASA has no formalized requirements for integrating human health and research among life sciences subject matter experts nor does it maintain a centralized point of coordination to identify key integration points for human health. Moreover, integrating the experiences of NASA's engineering and safety efforts would benefit the outside life sciences community. The lack of a coordinated, integrated, and strategic approach may result in more time consuming and costly efforts to develop countermeasures to the numerous human health and performance risks associated with deep space missions.

Long duration missions will likely expose crews to health and human performance risks for which NASA has limited effective countermeasures. Accordingly, for these missions NASA will have to determine the level of risk that is acceptable and clearly communicate the Agency's decisions to astronauts, Congress, and the public. Moreover, NASA needs to continue to examine whether its current health care model for astronauts is sufficient to meet both the long-term health needs of the astronaut community and the research needs of the Agency.

WHAT WE RECOMMENDED

To ensure NASA management has the best possible information available to make decisions related to human health and performance risks to Agency missions, we recommended the Manager of HRP ensure (1) HRP costs for research and countermeasure development are accurate and (2) the Path to Risk Reduction accurately reflects the status of research and realistic timeframes for countermeasure development to better determine what risks will be mitigated for the first human mission to Mars. In addition, to ensure appropriate integration of Agency expertise across disciplines, we recommended the Associate Administrator for HEOMD (3) establish a primary point of coordination within HEOMD to interface with all NASA programs, projects, and functions; (4) ensure that integration of technical authorities is occurring and consider inclusion of engineering and safety experts on all HHP and HRP control boards; and (5) clarify the organizational technology development responsibilities for human system risk mitigation. Regarding astronaut health care, we recommended the NASA Administrator and the Chief Health and Medical Officer (6) determine whether the current model satisfies Agency needs and the needs of the astronaut community and, if not, pursue legislative authority to implement necessary changes.

In response to a draft of our report, management concurred or partially concurred with our recommendations and described corrective actions they plan to address them. We consider management's comments responsive; therefore, the recommendations are resolved and will be closed upon completion and verification of the proposed corrective actions.

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Acronyms

CHMO	Chief Health and Medical Officer
CMO	Chief Medical Officer
DRM	Design Reference Mission
FY	Fiscal Year
HEOMD	Human Explorations and Operations Mission Directorate
HERA	Human Exploration Research Analog
HMTA	Health and Medical Technical Authority
HHP	Human Health and Performance
HRP	Human Research Program
HSRB	Human System Risk Board
IOM	Institute of Medicine
ISS	International Space Station
LSAH	Longitudinal Study of Astronaut Health
NPR	NASA Procedural Requirements
NSBRI	National Space Biomedical Research Institute
PRR	Path to Risk Reduction
OCHMO	Office of the Chief Health and Medical Officer
VIIP	Vision Impairment and Intracranial Pressure

INTRODUCTION

Space flight is an inherently risky endeavor. Apart from the tremendous engineering challenges in launching and returning astronauts safely to Earth, humans living in space experience a range of physiological changes that can affect their ability to perform necessary mission functions and, in the long term, increased risk of developing cancer, damaged vision, reduced bone strength, and other damage to their health and wellbeing. Moreover, despite efforts over the last 40 years to characterize and study the risks posed by space travel, many are not fully understood. Although NASA has developed mitigation strategies to reduce the impact of most of the risks associated with travel in low Earth orbit, the Agency's plans to send humans deeper into space for extended periods of time will expose astronauts to new and increased risks.

To further understand the risks to human health and performance associated with space travel, NASA and its partners are performing a variety of studies on Earth and the International Space Station (ISS). For example, in March 2015, NASA launched astronaut Scott Kelly on the first one-year mission to the ISS. NASA will compare health data taken from Scott Kelly with that of his twin brother and former astronaut, Mark Kelly, in the hope of advancing knowledge about the effects on the human body of long duration habitation in space.

In this audit, we examined NASA's efforts to manage the health and human performance risks posed by space exploration. See Appendix A for details of the audit's scope and methodology.

Background

The Path to Mars

NASA's space exploration goal is to conduct a crewed mission to the surface of Mars by the 2030s. Given the difficulty of such a journey, NASA has indicated it will take a flexible path to Mars that evolves based on lessons learned from prior and current missions. The NASA Authorization Act of 2010 endorses this approach as an incremental method of progressively traveling, living, and working deeper in space and developing capabilities that will allow space system components to be used for multiple and varied missions. In this regard, NASA plans to test new systems and technologies in cis-lunar orbit before traveling to near-Earth asteroids and beyond.¹ By 2027, NASA hopes to establish a formal Mars Program and begin human flights to the planet by the middle of the following decade.

Moving the space frontier from low Earth orbit to deep space will be a significant undertaking. For perspective, low Earth orbit is the area extending approximately 200 – 1200 miles from the Earth's surface, while the Moon is 237,000 miles away. Astronauts on missions in these areas of space are

¹ Cis-lunar is the area between Earth and the Moon or the Moon's orbit.

within a couple of days of return to Earth and, when living on the ISS, receive regular resupply missions. In contrast, Mars is almost 34 million miles from Earth, and a round trip to the planet is likely to take up to 3 years through harsh conditions, making resupply and quick return to Earth in case of emergency impossible.

NASA’s Health and Medical Technical Authority (HMTA) has developed design reference missions (DRM) for each type of mission along the flexible path to Mars: low Earth orbit, deep space sortie, lunar visit or habitation, deep space journey or habitation, and planetary.² The DRMs provide a framework to help the HMTA identify capabilities, drivers, and assumptions for each mission type. Although the missions share some of the same human health and performance challenges, each also poses unique challenges. Key factors distinguishing the various DRMs include distance traveled from the Earth, abort time (i.e., the time it takes to return to Earth in the case of emergency), and duration. See Table 1 for more information about the various DRMs.

Table 1: Design Reference Missions for Flexible Path

Design Reference Mission	Mission Duration	Distance from Earth (in miles)	Earth Return	Gravity Environment	Radiation Environment
Low Earth Orbit (ISS)	6 months	237	less than or equal to 1 day	Microgravity	Low Earth Orbit
Low Earth Orbit (ISS)	1 year	237	less than or equal to 1 day	Microgravity	Low Earth Orbit
Deep Space Sortie	1 month	greater than 237,000	less than 5 days	Microgravity	Deep Space
Lunar Visit or Habitation	1 year	237,000	5 days	1/6 G	Lunar
Deep Space Journey or Near-Earth Asteroid	1 year	237,000 – 33,900,000	weeks to months	Microgravity	Deep Space
Planetary	3 years	33,900,000 ^a	months	Fractional	Deep Space

Source: NASA.

^a Planetary distance is based on the distance of Mars from Earth.

Hazards Associated with Deep Space Exploration

With relation to human travel, the deep space environment differs from low Earth orbit in several important respects: (1) it likely poses risks that have not yet been identified (unknown risks); (2) ways to mitigate many of the known risks have yet to be developed; and (3) humans will not be able to communicate with Earth in-real time or return to Earth quickly in case of emergency. Hazards of deep space travel include:

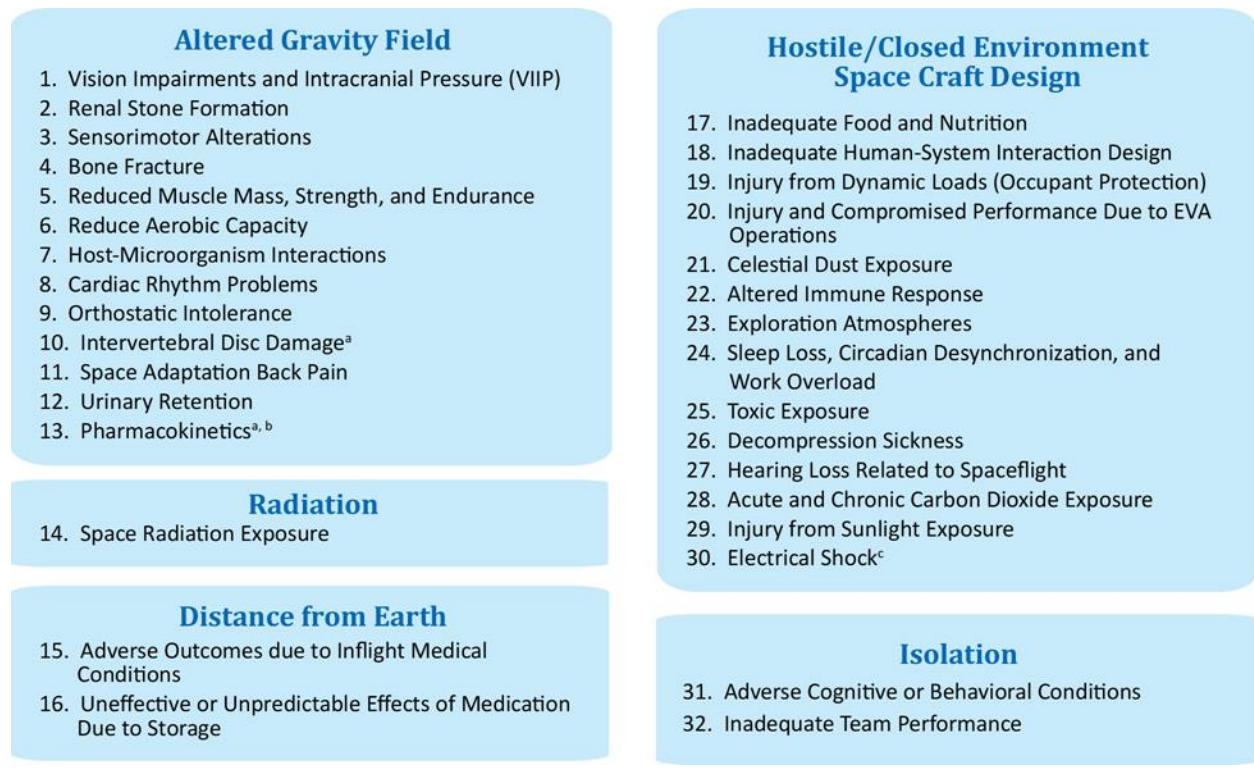
- *Limited resources.* Storage, power, and weight limitations in the crafts in which humans will travel and live in deep space will affect the amount and type of food, medical supplies, exercise equipment, and other resources available.

² HMTA provides independent oversight of all health, medical, and space crew/personnel performance matters related to NASA programs or projects.

- *Isolation.* Because crews will be millions of miles and many months travel from Earth, they must be prepared to deal with a variety of medical situations ranging from minor cuts to catastrophic injuries. In addition, isolation from Earth may cause psychological and behavioral issues for crew members that could affect their wellbeing and performance. Finally, the periodic deliveries of supplies available to crews living on the ISS will not be an option in deep space.
- *Hostile/closed environment spacecraft design.* Spacecraft will have a closed life-support system and cramped working and living quarters. The ISS has 15,000 cubic feet of habitable area – more than a conventional 3-bedroom house. In contrast, the Orion crew capsule NASA is developing and plans to use for at least the initial forays beyond low Earth orbit has 314 cubic feet of habitable area.
- *Altered gravity.* The prolonged weightlessness experienced in space causes astronauts to endure a number of physical and physiological changes. For example, astronauts routinely experience altered inner ear function as well as loss of bone density and muscle strength and blood and other bodily fluids move from the legs and lower extremities to the upper parts of the body.
- *Space radiation.* Deep space radiation is significantly different from radiation encountered on Earth, and it is unknown how the human body will respond to prolonged exposure. Earth, and to a lesser extent low Earth orbit, are protected by the Van Allen Belts, regions of trapped radiation held in place by the Earth's magnetic field that shield the planet and its human inhabitants from space radiation and solar weather. Missions that travel beyond low Earth orbit do not enjoy the protection of the Belts.

As depicted in Figure 1, NASA has identified 30 human health and performance risks emanating from these primary hazards. In addition, the Agency has identified 2 other issues it has not yet accepted as risks and therefore labels concerns. For detailed information on each of the risks, see Appendix B.

Figure 1: Human Health and Performance Risks by Space Environment Hazard



Source: Human Research Program, 2015.

^a Concern.

^b Pharmacokinetics is the study of the movement of drugs in the body.

^c Risk has been retired.

NASA Organizations that Manage Human Health and Performance Risks

Multiple NASA offices play a role in developing procedures, medications, devices, and other strategies (countermeasures) to mitigate the adverse health and human performance risks of traveling and living in space. Most of these offices are part of the Agency’s Human Explorations and Operations Mission Directorate (HEOMD). In addition to HEOMD components, the Office of the Chief Health and Medical Officer (OCHMO) defines the level of risk NASA will accept for its astronauts by setting standards for such issues as maximum radiation exposure levels and required hours of sleep during a mission.

Office of the Chief Health and Medical Officer

The OCHMO establishes NASA’s health and medical policy and related procedural requirements and technical standards. The Chief Health and Medical Officer (CHMO) serves as the focal point for policy formulation, oversight, coordination, and management of all health and medical matters and as the principal advisor to the Administrator and other senior officials on matters pertaining to human health. By policy, he or she also serves as NASA’s lead HMTA, providing independent oversight of all health, medical, and space crew/personnel performance matters that arise in association with NASA programs

or projects.³ The CHMO has delegated HMTA responsibilities for human space flight to the Johnson Space Center (Johnson) Chief Medical Officer (CMO). Any deviations from OCHMO policy, requirements, and standards may be made only with concurrence of the HMTA.

Human Exploration and Operations Mission Directorate

HEOMD provides leadership and management of NASA's human space exploration programs, and several HEOMD divisions share responsibility for issues relating to human health and performance. The Space Life and Physical Sciences Research and Applications Division at NASA Headquarters oversees basic and mission driven scientific research in support of human space flight and is comprised of three major components – Space Life Sciences, Physical Sciences, and Human Research Program (HRP). The Human Spaceflight Capabilities Division includes Crew Health and Safety. The two divisions work with the Office of the Chief Scientist to establish the overall direction, scope, budget, and resource allocation for managing activities that support astronaut health and safety for space flight operations, including pre- and post-flight performance. HEOMD-sponsored life sciences research is managed primarily at Johnson, Ames Research Center, Glenn Research Center, and Langley Research Center, with supporting infrastructure and plant research performed at the Kennedy Space Center.

Human Health and Performance Directorate

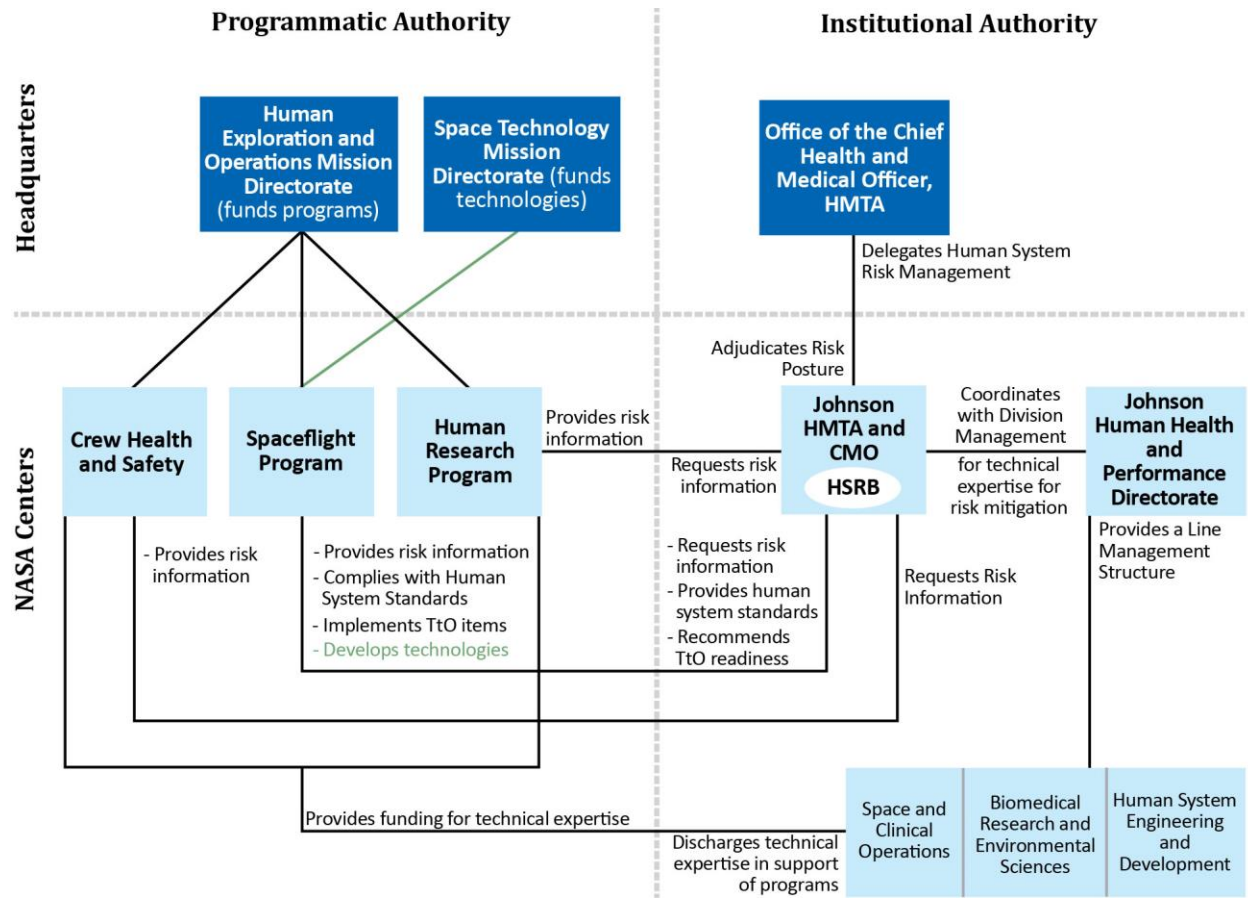
Based at Johnson and reporting to the Johnson Center Director and the HEOMD Associate Administrator, the Human Health and Performance (HHP) Directorate serves as the Agency's primary resource for human health and performance issues. HHP's strategic goals are aimed at leading human exploration and ISS utilization, leading human health and performance internationally, excelling in management and advancement of innovations in health and human system integration, and expanding relevance to life on Earth and creating enduring support and enthusiasm for space exploration. HHP was reorganized in 2012 to integrate research and development with space flight operations to better support human space flight and utilization of the ISS for related research.

Human Research Program

NASA established HRP at Johnson in October 2005 to focus Agency research investment on investigating and mitigating the highest risks to astronaut health and performance. HEOMD and OCHMO are HRP's two primary customers. While HRP resides within and relies on the infrastructure and staff of HHP, it is considered a separate program and reports directly to HEOMD (see Figure 2 for a description of the organizational relationship).

³ NASA established technical authorities in a variety of areas to provide independent oversight of programs and projects to support safety and mission success in response to recommendations made in 2003 by the Columbia Accident Investigation Board.

Figure 2: Human Explorations and Operations, Human Research Program, and Human Health and Performance Directorate Organizational Structure



Source: Johnson HMTA.

Note: Programmatic authority consists of the mission directorates and their respective programs and projects. Institutional authority includes the Headquarters and Center mission support organizations, technical authorities (in this case HMTA), and Center Directors. Further, HSRB refers to the Human System Risk Board and TtO refers to Transition to Operations.

HRP conducts basic, applied, and operational research with the goal of increasing understanding of and developing countermeasures for 23 of the human health and performance risks and the 2 concerns NASA has identified.⁴ HRP organizes its research into five “Risk Elements” that encompass the risks and concerns:

1. Behavioral Health and Performance
2. Exploration Medical Capability
3. Human Health Countermeasures

⁴ Generally, HRP accomplishes its research through either directed or solicited research tasks. Directed research is carried out by the Agency and external researchers who have been selected through noncompetitive mechanisms such as contracts and grants. Research may be directed instead of solicited due to time limitations, highly focused or constrained research topics, or because in-house experts are better suited to conduct it. Conversely, solicited research tasks are awarded through competitive means such as NASA Research Announcements or Requests for Proposals. HRP reports that approximately 80 percent of the research it sponsored in fiscal year (FY) 2014 was solicited.

4. Space Human Factors and Habitability
5. Space Radiation⁵

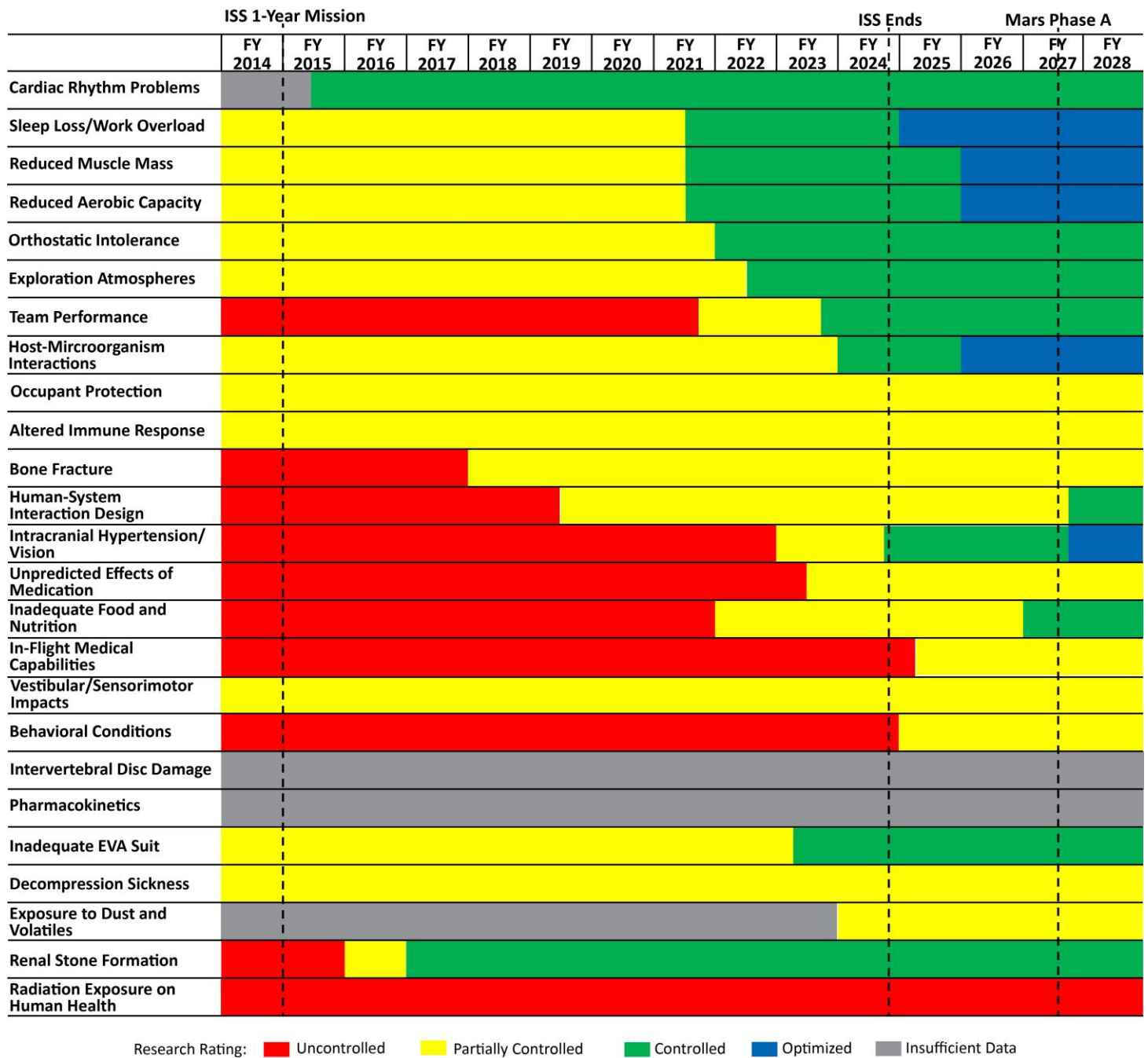
HHP and HRP staff tasked with managing specific risks are called “risk owners.” The process for identifying and mitigating risks begins with risk owners collecting evidence and developing an Evidence Report for each risk. As part of that process, they identify the knowledge gaps relating to a particular risk and the tasks necessary to close those gaps and document this information in an Element Research Plan. These Plans detail when, where (e.g., the ISS or a ground analog), and who will accomplish the tasks and the products they will produce. Using Element Research Plans, risk owners direct internal principal investigators or solicit external experts to complete tasks by developing an Integrated Research Plan. Upon receipt of the research results, risk owners revise Evidence Reports to reflect the new information and continue working the issue until the risk is deemed fully mitigated. Throughout the process, HMTA and the Human System Risk Board (HSRB) help risk owners prioritize research tasks and monitor progress toward mitigation.

HRP tracks the likelihood of occurrence, severity of consequences, and the extent a risk can be controlled or mitigated both in-flight and post flight for the various DRMs. This tracking serves as one of several inputs that determines the priority of each risk and the resulting allocation of resources. The extent to which a particular risk can be mitigated is determined by considering the current state of knowledge about the risk; existing standards, if any; and the degree to which proven or potential countermeasures will enable NASA to meet those standards. NASA labels risks based on whether they can be mitigated to meet existing standards. Risks that can be mitigated beyond what the standards require are referred to as “optimized.” Risks that can be mitigated to meet the standards are considered “controlled” and therefore “acceptable.” Risks for which some validated countermeasures exist but additional mitigation is required to meet standards are “partially controlled” and therefore “unacceptable.” Finally, risks that lack any validated countermeasures are “uncontrolled” and therefore “unacceptable.”

In 2014, HRP completed a detailed schedule setting forth the rate by which HRP expects to complete development of countermeasures for the risks and concerns assigned to it over a 15-year period (i.e., through 2028) known as the Path to Risk Reduction (PRR). The PRR summarizes the Agency’s ability to control the risks and concerns based on current understanding and identification and validation of potential countermeasures. NASA updated the PRR in June 2015. According to the 2015 version of the document, the Agency will lack validated countermeasures for 11 of the 23 identified risks and both of the 2 concerns in time for a Mars mission in the 2030s (see Figure 3).

⁵ The following risks do not fall under HRP’s purview: (1) Space Adaptation Back Pain, (2) Urinary Retention, (3) Toxic Exposure, (4) Hearing Loss Related to Spaceflight, (5) Acute and Chronic Carbon Dioxide Exposure, (6) Injury from Sunlight Exposure, and (7) Electrical Shock.

Figure 3: HRP Path to Risk Reduction for a Planetary Mission



Source: HSRB, June 2015, PRR Revision C.

National Space Biomedical Research Institute

The National Space Biomedical Research Institute (NSBRI) assists NASA in identifying, selecting, and conducting research associated with space exploration mission risks. Formed in 1997 and operating under a cooperative agreement with the Agency, NSBRI is a nonprofit research partner of HRP that connects the research, technical, and clinical expertise of the biomedical community with the scientific, engineering, and operational expertise of NASA. NASA and NSBRI jointly plan annual solicitations targeted at research and technology development to reduce human-related exploration risks.

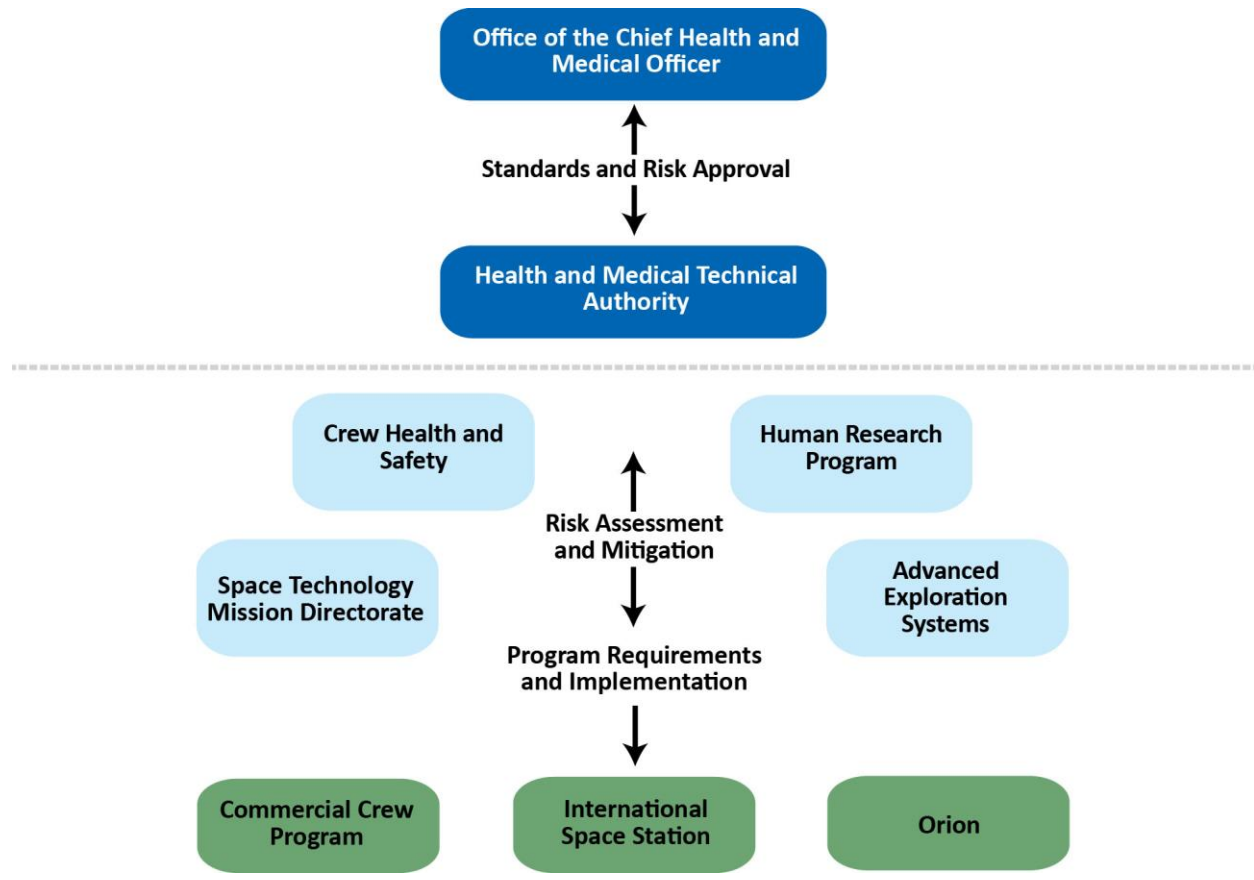
Human System Risk Board

HSRB is another key player in managing space-related human health and performance risks. Established in 2012 and chaired by the Johnson CMO, HSRB provides a venue for the discussion and exchange of data and information among stakeholders and has overall responsibility for implementing a consistent, integrated process for managing human system risks. In addition, HSRB acts as the HMTA Control Board or decision-making body, identifying risks and concerns, evaluating and approving evidence-based risk assessments, endorsing cross-program and multidisciplinary plans, determining whether countermeasures satisfy standards, and documenting and tracking management activities. HSRB is also charged with establishing official HMTA positions on risk posture and deciding the work that will be performed to address risk mitigation and improve risk posture. One of the tools HSRB uses is the PRR.

NASA Health Standards

NASA's health standards are based on the best available scientific and clinical evidence and expert recommendations, including medical practice, lessons learned, comparable environments and populations (analog), research findings, and risk management data. The standards are documented in two volumes: NASA-STD-3001, Volume 1 and 2. The first volume sets requirements for fitness for duty, permissible exposure limits, permissible outcome limits, levels of medical care, medical diagnosis, intervention and treatment, and care. For example, one fitness for duty standard is that crewmembers maintain 80 percent of their baseline muscle strength during a mission. The second volume defines standards for spacecraft, including habitats, suits, related equipment, and software systems and informs requirements for the ISS, the commercial vehicles NASA hopes will ferry crew to the ISS starting in 2017, Orion, and any vehicles developed in the future. Figure 4 illustrates NASA's process for identifying risks and developing standards, mitigation, and program requirements.

Figure 4: Overview of Process for Identifying Risk and Developing Standards, Mitigation and Program Requirements



Source: Human Research Program.

The Role of the Institute of Medicine

Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine (IOM) provides independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public. In its review of NASA health-related issues, the IOM has found that HRP is taking the right approach in developing mitigation strategies for the various space travel-related risks. For example, in 2008, the IOM reported that Evidence Reports are valuable resources and important components in the overall risk mitigation process. Since 2008, the IOM has reviewed each risk once and will continue to review a few selected risks each year until all 23 risks under HRP purview have undergone a second review.

Although NASA has sponsored numerous IOM reviews, three bear particular significance to the subject of this report: “Safe Passage: Astronaut Care for Exploration Missions;” “Review of NASA’s Longitudinal Study of Astronaut Health;” and “Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework.”

Safe Passage: Astronaut Care for Exploration Missions

In response to a request from NASA, the IOM convened the Committee on Creating a Vision for Space Medicine During Travel Beyond Earth Orbit to address astronaut health. This Committee was charged with making recommendations regarding the infrastructure for a health system in space, defining the principles that should guide such a system to provide an appropriate standard of care for astronauts, and identifying the nature of clinical and health services research that will be required before and during long duration missions. The resulting 2001 report, “Safe Passage: Astronaut Care for Exploration Missions,” made seven recommendations to improve NASA’s medical care system and develop the infrastructure needed to support long duration missions:

1. Give increased priority to understanding, mitigating, and communicating to the public the health risks of long duration missions beyond Earth orbit.
2. Develop a comprehensive health care system for astronauts for the purpose of collecting and analyzing data while providing the full continuum of health care to ensure astronaut health.
3. Develop a strategic health care research plan designed to increase the knowledge base about the risks to astronaut health.
4. Give priority to increasing the knowledge base of the effects of living conditions and behavioral interactions on the health and performance of astronauts on long duration space missions.
5. Develop and use an occupational health model for the collection and analysis of astronaut health related data, giving priority to the creation and maintenance of a safe work environment.
6. Accelerate integration of Agency engineering and health sciences cultures.
7. Establish an organizational component headed by an official who has authority over and accountability for all aspects of astronaut health, including appropriate policy-making, operational, and budgetary authority.

Review of NASA’s Longitudinal Study of Astronaut Health

In 1992, NASA designed a protocol known as the Longitudinal Study of Astronaut Health to examine the long-term effects of space flight and the overall health-related risks associated with working as an astronaut. The Study investigates the incidence of acute and chronic illness and astronaut deaths to determine whether the unique occupational exposures of space flight are associated with increased risk. NASA requested assistance from the IOM in assessing the progress of the study and making any necessary midcourse corrections. In January 2004, the IOM issued “Review of NASA’s Longitudinal Study of Astronaut Health” and made recommendations for improving the Study and recommended that NASA “assume responsibility for the lifelong healthcare of active and former astronauts.” Currently, NASA provides comprehensive health exams to active astronauts to ensure they are “flight ready” and, once an astronaut retires, offers occupational surveillance screenings like blood chemistry panels and ocular assessments. However, beyond these services, retired astronauts are entitled only to the standard benefits provided to all Federal civil servants and military personnel – benefits that are tied to length of service and retirement age. Moreover, once astronauts retire and receive health care elsewhere, NASA may lose access to important medical data that can further knowledge about the long-term human health risks of space travel.

Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework

In 2014, the IOM issued “Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework,” which sets forth a framework of ethical and policy principles to help guide NASA’s decision making surrounding the implementation of crew health standards for long duration missions. Among other issues, the study addressed the appropriate course of action when existing NASA standards for radiation exposure or other health and safety issues cannot be fully met or the level of knowledge concerning a particular condition is sufficiently limited that an adequate standard cannot be developed.⁶

⁶ In response, NASA drafted an implementation plan to address the ethical framework concerns highlighted in the report. The implementation plan remains in draft and has not been approved by the Administrator as of September 1, 2015.

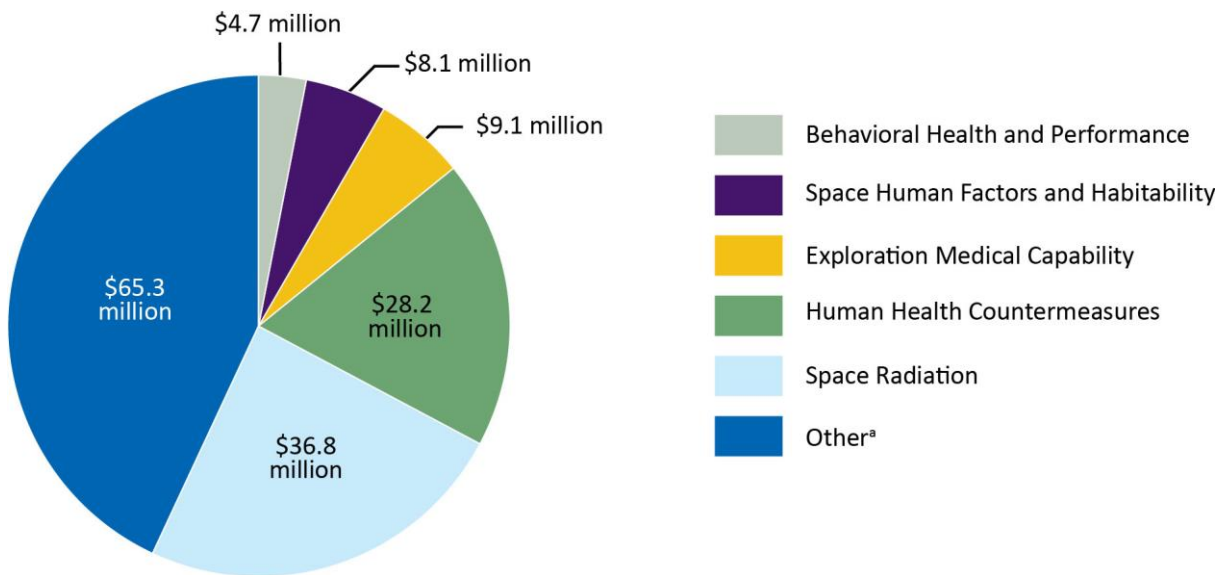
CHALLENGES DELAY RESEARCH AND IMPACT DEVELOPMENT OF MITIGATION STRATEGIES

Although NASA continues to improve its process for identifying and managing health and human performance risks associated with space flight, we believe that given the current state of knowledge, HRP's schedule for mitigating its top risks is optimistic and the Agency will not develop countermeasures for many deep space risks until the 2030s, at the earliest. One of the major factors limiting more timely development of countermeasures is uncertainty about the mass, volume, and weight requirements of deep space vehicles and habitats – in essence, NASA is trying to develop countermeasures for an environment it does not yet fully understand. Moreover, even as NASA gains additional knowledge about those vehicles and habitats and the effects of radiation and other space conditions on the human body, the Agency may be unable to develop countermeasures that will lower the risk to deep space travelers to a level commensurate with Agency standards for low Earth orbit missions. Accordingly, the astronauts chosen to make at least the initial forays into deep space may have to accept a higher level of risk than those who fly ISS missions. We also found that NASA could not accurately report the true costs of developing countermeasures for the identified risks.

NASA's Management of Human Health and Performance Risks

HRP management creates a budget for each of the five risk elements (Behavioral Health and Performance, Exploration Medical Capability, Human Health Countermeasures, Space Human Factors and Habitability, and Space Radiation) that element risk managers must allocate among their various research tasks. In fiscal year (FY) 2014, HRP spent a total of \$152.2 million on the 5 research elements: \$86.9 million on 120 active research tasks and \$65.3 million on programmatic costs, such as infrastructure and travel. Figure 5 shows HRP's FY 2014 costs by risk category.

Figure 5: Human Research Program FY 2014 Spending



Source: NASA.

^aOther funding includes ISS Medical Projects and HRP infrastructure and management costs.

Despite these reported budget figures, the true cost of mitigating the various risks is unclear because some research tasks are connected to multiple risks and rely on programs outside of HRP, and therefore are funded from multiple sources. For example, research tasks associated with the Inadequate Food and Nutrition risk receive funds from both the Human Health Countermeasures and Space Human Factors and Habitability elements, and the Space Radiation Program relies on HRP funding, as well as, the ISS Program Office and the Advanced Exploration Systems Program. Specifically, the 5-year space radiation budget for FYs 2014 through 2019 was approximately \$238 million, only \$198.5 million of which came from HRP with the rest provided by the ISS Program, Advanced Exploration Systems, Space Technology Mission Directorate, and Crew Health and Safety Office.

HHP is starting to clarify the cost associated with mitigating the various risks by implementing a budget-reporting requirement for the HSRB reviews. However, we found that the February 2015 HSRB review did not include budget information for the Behavioral Health and Performance, Inadequate Food and Nutrition, and Human-System Interaction Design risks. More complete information about the true cost of mitigation efforts would improve HRP's ability to plan and conduct research and help avoid delays caused by unexpected funding shortages.

Progress Made to Mitigate Risks, but Many Gaps Remain

HSRB measures progress on risk reduction by determining whether in-flight and post-mission health and performance effects can be mitigated to an acceptable level as defined by NASA health and performance standards. In February 2015, HRP reported that of the health and human performance risks they research, the majority of risks for ISS missions up to a year in duration could be mitigated to an acceptable level. However, more than half of the risks for a 3-year planetary mission, such as a trip to Mars, remain unmitigated. Table 2 shows the 30 HHP risks as of February 2015 NASA can mitigate to

an acceptable level (Accepted) and those that still require countermeasures to be developed or validated to meet existing health standards (Requires Mitigation). While some risks can be mitigated for the duration of a mission, they may still require mitigation for post-mission effects.

Table 2: Risks Mitigated to an Acceptable Level for Selected Design Reference Missions

Design Reference Mission	Accepted for In-Flight	Requires Mitigation for In-Flight	Accepted for Post-Mission	Requires Mitigation for Post-Mission
Low Earth Orbit (6 months) ^a	28	1	26	2
Low Earth Orbit (1 year) ^a	27	2	26	2
Lunar Visit Habitation (1 year)	23	7	22	7
Planetary (3 years) ^b	9	20	11	17

Source: Human System Risks Summary Charts, HMTA, February 2015.

Note: The table reflects 30 HHP risks, only 23 of which are assigned to HRP. There is insufficient information about the Space Adaptation Back Pain to determine the mitigation status for post-flight risks.

^a The Celestial Dust Exposure risk is not applicable to the ISS because crew is not exposed to such dust.

^b The acceptance of the Celestial Dust Exposure risk is to be determined for a planetary mission; therefore, a decision on acceptance level has yet to be determined.

Over the next 13 years, HRP expects to develop countermeasures for and bring to an acceptable level most of the risks associated with a human mission to Mars. However, several HRP researchers we spoke with characterized the PRR as overly optimistic and believe it will take longer than NASA anticipates to reach the acceptable level for several risks. Moreover, according to the CHMO, although NASA will not waive the existing standards applicable to low Earth orbit missions for a Mars mission, it will likely seek exceptions to the standards for some risks.

We selected six specific risks in various stages of maturity and countermeasure development from four risk areas: (1) Behavioral Health and Performance, (2) Inadequate Food and Nutrition, (3) Space Radiation, and (4) Vision Impairment and Intracranial Pressure (VIIP). To gain an understanding of how NASA addresses these risks, we analyzed the Agency’s current and planned research. Based on information the HMTA presented at a February 2015 HSRB meeting, NASA has countermeasures to mitigate to an acceptable level all short-term effects for the six risks associated with an ISS mission of 6 months or less. In contrast, for a planetary mission, NASA had accepted only the space radiation risks during flight. We found that progress in mitigating risks varied based on the current level of knowledge, available countermeasures, and the extent to which the deep space environment differs from low Earth orbit.

Behavioral Health and Performance

We examined NASA’s efforts to address three specific Behavioral Health and Performance risks: (1) adverse cognitive and behavioral conditions, (2) sleep loss, and (3) poor team cohesion and performance. Lack of privacy; isolation from family, friends, and the familiarity of Earth; and shorter, less restful and more interrupted sleep can negatively affect astronauts’ physical and mental health both during and after a mission. For example, during a mission crew cohesion may be affected, long-term

sleep loss can lead to hypertension, diabetes, obesity, heart attack, stroke, and psychiatric disorders such as depression or severe anxiety may occur. Although conflict among crew members has been relatively infrequent during ISS missions, these issues may take on more significance with longer duration missions and in more closely confined spaces.

NASA has used environmental factors, crew selection requirements, training, workload scheduling, medicine, and communication with support networks to counter these risks. For example, the ISS has private crew quarters and Earth-viewing windows to help astronauts cope with lack of privacy and isolation from Earth. In addition, NASA has established standards for a normal, uninterrupted sleep period and limited the amount of work astronauts can perform in a day and week to an average of 6.5 and 48 hours, respectively.⁷ NASA also works to identify crew members who are well suited to working in teams. Finally, astronauts are given medications to prevent and treat motion sickness, sleep problems, illnesses, and injuries.

Earth viewing window on ISS



Source: NASA.

Anecdotal and empirical evidence from NASA and external studies indicate that the likelihood a behavioral concern or psychiatric disorder will occur during a mission increases with mission length. Several of the countermeasures NASA uses to combat these risks on ISS missions – such as real-time communication with Mission Control and care packages from family members – will not be available during a Mars mission. Unlike for the ISS, there will be no regular resupply missions on a Mars trip and communications between Earth and Mars could take up to 44 minutes roundtrip. Moreover, sleep and non-sleep medications may be required in-flight, and the potential interactions between these and other medications needed to mitigate other deep space risks have yet to be determined. Table 3 shows by DRM the extent to which behavioral risks have been accepted and the associated consequence (from very low to high) should the risk occur.

⁷ According to NASA-STD-3001 Vol.1, an overloaded workload is defined as a 10-hour workday for more than 3 days a week or more than 60 hours for a workweek.

Table 3: Behavioral Health and Performance In-Mission and Post-Mission Risks

		Low Earth Orbit (6 months)	Low Earth Orbit (1 year)	Lunar Visit (1 year)	Asteroid (1 year)	Planetary (3 years)
Cognitive or Behavioral Conditions	In-Mission Risk	Accepted	Requires Mitigation	Requires Mitigation	Requires Mitigation	Requires Mitigation
	Post-Mission Risk	Accepted	Accepted	Accepted	Accepted	Requires Mitigation
Sleep Loss	In-Mission Risk	Accepted	Accepted	Accepted	Requires Mitigation	Requires Mitigation
	Post-Mission Risk	Accepted	Accepted	Accepted	Requires Mitigation	Requires Mitigation
Team Performance	In-Mission Risk	Accepted	Accepted	Accepted	Accepted	Requires Mitigation
	Post-Mission Risk	Accepted	Accepted	Accepted	Accepted	Accepted

Source: Human System Risks Summary Charts, HMTA, January 2015.

Legend: ■ High consequences ■ Low to medium consequences ■ Very low to low consequences

In FY 2014, HRP funded 32 research tasks aimed at helping to close knowledge gaps associated with these behavioral risks, including ways in which astronauts can most effectively and safely use medications to promote sleep and alertness; acceptable thresholds of team function for autonomous, long duration or distance missions; how personal relations with family, friends, and colleagues affect behavioral health and performance during long duration missions; and identifying biomarkers that indicate the presence of a medical condition or disease.⁸ In addition, NASA constructed the Human Exploration Research Analog (HERA), a facility at Johnson that allows research subjects to be placed in isolated and confined environments for up to a month. Using the HERA facility, NASA has run several scenarios and is planning an uninterrupted stay of one month. Furthermore, in August 2015, a six-person team began a year stay locked in an isolation dome as part of the Hawaii Space Exploration Analog and Simulation. As of August 2015, NASA does not have a validated mitigation strategy for any of the behavioral risks for a Mars mission. According to the June 2015 PRR, HRP plans to validate countermeasures for sleep loss in FY 2021 and for team performance by FY 2023, in time for NASA to designate both risk as accepted for an early 2030s Mars mission. However, the behavioral condition risk will only be partially controlled by FY 2027, and it is unclear whether it will be accepted by the early 2030s.

Nutrition and Food System

Ensuring adequate nutrition for humans living and traveling in space is critical. Despite 35 years of experience with space flight and research in this area, NASA food scientists continue to face challenges from crew member weight loss, dehydration, and reduced appetite that can result in nutrient deficiencies both during and post mission. Although these issues are a concern for all missions, it is

⁸ A biomarker is a biologic feature that can be used to measure the presence or progress of disease or the effects of treatment. For example, prostate specific antigen is a biomarker for prostate cancer.

relatively easy for astronauts who return to Earth after a year or less in space to regain their nutritional baselines with little impact on their long-term health. However, NASA does not know whether this will be the case for a Mars mission.

NASA has not yet developed a validated strategy for overcoming nutritional risks for a planetary mission lasting up to 3 years. For the ISS, NASA sustains crews with prepackaged food supplemented with limited fresh food delivered during periodic resupply missions. As mission length and distance from the Earth increases, such a system will not be sufficient to meet astronaut nutritional needs. First, the current shelf life for prepackaged foods is only 1.5 years, and several key nutrients in many foods start to degrade even earlier. Second, because any vehicle traveling to Mars will likely be significantly smaller than the ISS, mass, volume, waste, and disposal issues associated with current food packaging must be addressed. Third, periodic resupply missions bringing fresh supplies will not be feasible. Finally, scientists do not know how deep space radiation will affect the quality and nutritional value of food. NASA is investigating countermeasures for these risks, including growing food in the vehicle during the mission and alternative storage solutions such as processing foods at lower temperatures to better preserve nutrients and increase shelf life. Table 4 shows by DRM the extent to which food and nutrition risks have been accepted and the associated consequences.

Table 4: Inadequate Food and Nutrition In-Mission and Post-Mission Risk

		Low Earth Orbit (6 months)	Low Earth Orbit (1 year)	Lunar Visit (1 year)	Asteroid (1 year)	Planetary (3 years)
Inadequate Food and Nutrition	In-Mission Risk	Accepted	Accepted	Accepted	Accepted	Requires Mitigation
	Post-Mission Risk	Accepted	Accepted	Accepted	Accepted	Requires Mitigation

Source: Human System Risks Summary Charts, HMTA, January 2015.

Legend: ■ High consequences ■ Low to medium consequences ■ Very low to low consequences

In FY 2014, HRP funded 16 research tasks associated with food and nutrition to help answer 18 research gaps, including identifying the most important nutritional factors for cardiovascular health; how mission architecture and available countermeasures impact the nutritional status of crew; and methods, technologies, and requirements to deliver a food system that provides adequate safety, nutrition, and acceptability for long duration missions. For example, in 2014, NASA began investigating whether food can be grown onboard by testing a plant growth system on the ISS. In August 2015, ISS crew members sampled red romaine lettuce grown in the system. Researchers are evaluating several varieties of leafy vegetables with the goal of selecting those with the best growth, nutrition, and taste acceptability for an ISS mission; however, it is unknown whether growing food in deep space will differ from doing so in low Earth orbit.



HRP funding for nutrition research and countermeasure development is expected to end in 2020, at which time HRP plans to redirect those funds to developing a system to extend the shelf life of prepackaged foods to make them more suitable for long duration missions. NASA anticipates it will have validated countermeasures for all nutritional risks by FY 2027, which will allow it to accept the risks in time for a Mars mission in the early 2030s.

Space Radiation Exposure

Radiation in space comes from a variety of sources, including solar particle events and galactic cosmic rays, and is significantly different from the types of radiation encountered on Earth (e.g., gamma-rays and x-rays) that have lower energy and inflict less harm on the human body. Consequently, many uncertainties exist regarding how the human body will respond to exposure to space radiation. In addition to radiation sickness and cancer, other possible effects include central nervous system damage, cataracts, cardiovascular damage, inheritable effects, impaired wound healing, and infertility. HRP's Space Radiation Element covers four specific risks: (1) cancer, (2) changes in the central nervous system, (3) degenerative tissue diseases, and (4) acute radiation syndrome (e.g., nausea, vomiting, and fatigue). Some of these are immediate term risks that can affect crew performance and the success of a mission, while others are long-term issues that affect the length and quality of crew members' lives.

NASA's current radiation standard limits astronauts to a lifetime 3 percent risk of exposure-induced death for cancer mortality.⁹ This means that were 100 astronauts exposed to the upper bounds of the radiation limits, 3 would die of cancer attributable to that exposure. NASA research estimates that life expectancy for astronauts with radiation-induced cancer would be reduced by an average of 12 to 16 years. As part of its mitigation strategy, NASA currently sets short-term exposure limits to minimize acute effects that could impair a crew's ability to complete a mission.

Radiation countermeasures for ISS missions are preventative in nature and include shielding, limiting mission length, and predictive modeling that estimates spikes in radiation levels. Although similar countermeasures could be used for planetary missions, they may not be as effective in the deep space radiation environment. For example, experts generally agree shielding alone will not be sufficient to minimize exposure to galactic cosmic rays and biological and pharmacological countermeasures need to be explored.

Based on current knowledge, astronauts on a mission to Mars would exceed NASA's career radiation dosage limits. Although the Agency plans to continue efforts to develop countermeasures to address the radiation risk, NASA is likely to seek an exception from the current standards for those that cannot be fully mitigated.¹⁰ Table 5 shows by DRM the extent to which NASA has accepted space radiation risks and the associated consequences.

⁹ At the upper 95 percent confidence interval of the risk estimate.

¹⁰ NASA Advisory Council meeting, January 2015.

Table 5: Space Radiation Exposure In-Mission and Post-Mission Risk

		Low Earth Orbit (6 months)	Low Earth Orbit (1 year)	Lunar Visit (1 year)	Asteroid (1 year)	Planetary (3 years)
Space Radiation Exposure	In-Mission Risk	Accepted	Accepted	Accepted	Accepted	Accepted
	Post-Mission Risk	Accepted	Accepted	Requires Mitigation	Requires Mitigation	Requires Mitigation

Source: Human System Risks Summary Charts, HMTA, January 2015.

Legend: ■ High consequences ■ Low to medium consequences ■ Very low to low consequences

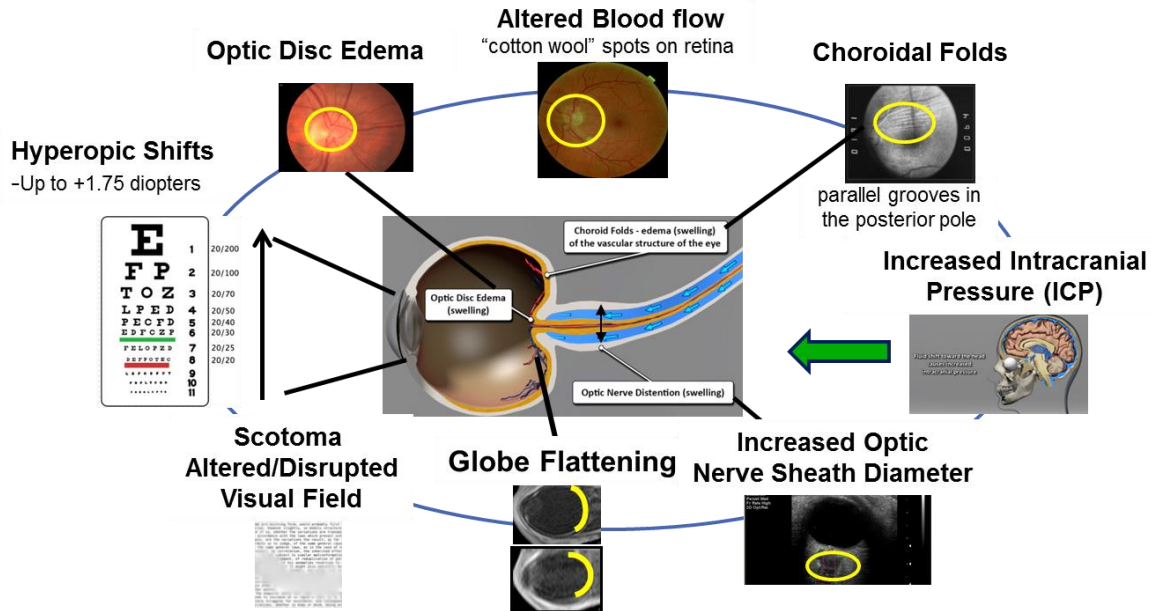
In FY 2014, HRP funded 55 research tasks to help close 38 knowledge gaps associated with space radiation exposure. Although HRP research has focused primarily on understanding cancer risk, the group plans to increase its focus on degenerative tissue diseases, an area with which NASA is less familiar. The Space Radiation Element recently received funds to upgrade a facility known as the Galactic Cosmic Ray Simulator to simulate the intense radiation that exists in space. In addition, risk owners have recently proposed developing a cardiovascular model as part of the FY 2016 testing plan that would estimate the effects of radiation on the human cardiovascular system without exposing human test subjects to radiation.

According to the June 2015 PRR, the space radiation risk remains uncontrolled for a planetary mission past FY 2027 due to limited knowledge about degenerative effects and the need to develop and validate countermeasures for post-mission risks; however, NASA has countermeasures in place for all in-flight radiation risks related to low Earth orbit missions.

Vision Impairment and Intracranial Pressure

Changes in vision during space flight have been documented through medical testing, research, and anecdotal reports by astronauts over the last 40 years. Based on data from 300 post-flight questionnaires, approximately 29 percent of short duration and 60 percent of long duration mission astronauts reported a degradation in vision and research has shown vision changes can occur after as little as 2 weeks aboard the ISS. In 2010, NASA formally identified VIIP as a space-related health risk. NASA believes that the microgravity environment of space leads to a shift in bodily fluids that creates intracranial pressure and that other factors such as resistive exercise, diet, medicines, and radiation may contribute to VIIP. The shift in fluids is also thought to lead to changes in vision and eye anatomy. Figure 6 shows the changes to vision and eye anatomy reported to date.

Figure 6: Reported Changes to Vision and Eye Anatomy Due to Space Flight



Source: NASA.

NASA requires a set of pre-, in-, and post-flight testing to determine the presence and degree of vision changes in astronauts and are utilizing new devices to image the back of and measure pressure in the eye. For treatment on orbit, corrective lenses are available. Additional potential countermeasures include pharmaceuticals, modified aerobic exercise, new mechanical devices to restrict blood flow to the head, reduced salt intake, and crew selection. Table 6 shows by DRM the extent to which the VIIP risk has been accepted and the associated consequence.

Table 6: Vision Impairment and Intracranial Pressure Risk

		Low Earth Orbit (6 months)	Low Earth Orbit (1 year)	Lunar Visit (1 year)	Asteroid (1 year)	Planetary (3 years)
Vision Impairment and Intracranial Pressure	In-Mission Risk	Accepted	Accepted	Accepted	Requires Mitigation	Requires Mitigation
	Post-Mission Risk	Accepted	Accepted	Accepted	Requires Mitigation	Requires Mitigation

Source: Human System Risk Summary Charts, HMTA, January 2015.

Legend: ■ High consequences ■ Low to medium consequences ■ Very low to low consequences

In FY 2014, HRP funded 19 research tasks to address 4 VIIP research gaps. In addition to the use of diagnostic tools to measure changes in the eye, ongoing studies include use of animal analogs, bed rest and other human microgravity analogs, computer modeling, technology development and flight certification, and in-flight studies involving crew members. According to the June 2015 PRR, NASA expects to have countermeasures to address VIIP risks in place by FY 2024.

Challenges Delay Progress in Identifying and Mitigating Risks

HRP faces inherent and programmatic challenges that may affect the pace at which knowledge gaps can be closed and risks mitigated before NASA attempts a Mars mission. Inherent challenges include unknowns associated with exploring a new space frontier, difficulty replicating the deep space environment on Earth, and knowledge gaps concerning how the various known human health and performance risks impact one another. Programmatic challenges include barriers to data sharing, limited time on the ISS to collect data, undefined health standards and vehicle requirements for a planetary mission, and funding constraints. As a result, NASA is not likely to develop countermeasures to mitigate all human health and behavioral risks to acceptable levels for a Mars mission by 2030 and Mars crews are likely to accept more risks than astronauts have in the past.

Although the PRR has only been in place since 2013, HRP has already revised the schedule twice and pushed out the mitigation schedules for some risks. For example, the original July 2013 PRR projected countermeasures to address the VIIP risk would be validated in FY 2022, while the June 2015 version shows a 2-year slip with validation occurring in FY 2024. Similarly, countermeasure validation for cancer, the central nervous system, and degenerative disease risks from space radiation exposure all moved from FY 2027 to FY 2029. Risk managers told us that some of the optimism in the initial PRR was attributable to the assumption that research aimed at closing knowledge gaps would yield the expected results, which is not always the case. We found that in developing the PRR, HRP did not consistently solicit input from engineers, flight operations, and other stakeholders involved in countermeasure development, which may also have contributed to schedule optimism.

Inherent Challenges

Predicting when knowledge gaps will be closed and countermeasures validated for the many risks associated with space travel is inherently complex. First, despite a nearly 50-year history of human travel in space, scientists do not fully understand many issues and there are many unknowns, particularly about extended human travel in deep space. Second, it is difficult to predict the pace of research breakthroughs and setbacks. Third, as was the case with VIIP, scientists may identify previously unknown risks, adding to the research agenda. Finally, as scientists learn more about the various risks, some risks grow in significance. For example, cancer was believed to be the most significant risk associated with radiation exposure, but research has shown that late central nervous system effects such as impaired motor skills and seizures may also be a major concern. Based on this research, the Space Radiation risk owner stated that the effects will take longer to understand – an additional 6 years – and as a result, the countermeasure validation date has been extended from FY 2027 to FY 2033.

Risks do not exist independently of one another, which makes research more challenging and less predictable. In its FY 2014 annual report, HRP noted that risks are generally studied in a segregated fashion, one system at a time, ignoring the strong connections between them. Although the IOM and standing review panels have noted relationships between risks, HRP has not developed a systematic approach to identify and investigate these relationships. HRP reported that it is in the early stages of addressing this problem, noting in its 2014 report that an integrated approach would help produce more efficient countermeasures to address multiple risks.

Risk owners stated that to date coordination among researchers has occurred as a result of informal contacts initiated by the researchers themselves. For example, researchers studying the Space Radiation and the Behavioral Health and Performance risks are coordinating to assess changes in sleep following radiation exposure. Similarly, Behavioral Health and Performance researchers are working with Inadequate Food and Nutrition researchers to assess how smell, variety, and choice of food affect mood and stress on long duration missions. Moreover, countermeasures developed for one risk may impact other risks, and researchers are starting to explore these types of connections. For example, sodium is often used as a food preservative. At the same time, HRP researchers are exploring whether reducing astronauts' sodium intake will decrease the intracranial pressure thought to contribute to VIIP.

Programmatic Challenges

NASA missions involve a relatively small group of astronauts and therefore provide a limited group for scientific study, in some instances no more than two individuals. For example, in March 2015, Scott Kelly began the first mission in which a U.S. astronaut will spend a full year living and working on the ISS. NASA will be collecting health data on him and his twin brother back on Earth in the hopes of learning more about the effects of long duration missions on the human body. However, the Kelly brothers and other small groups of astronauts may not reflect individual differences in the total population of the astronaut corps and therefore relying on information obtained from these studies could lead to inaccurate conclusions about how that larger population will react to risks and proposed countermeasures.

Other obstacles to collecting useful data include limited time and space for research on the ISS and concerns about privacy and how astronaut medical data will be used. Astronauts may be hesitant to share medical information if they perceive the information could jeopardize their chances of flying. Moreover, because of the relatively small size of the astronaut corps, it can be difficult to mask the identity of individual test subjects to ensure privacy and comply with applicable laws. Risk owners also told us that unless data collection is an operational requirement, it is considered voluntary and may be rescheduled for a later date due to a demanding workload. Finally, there are limitations on the number of experiments that can be conducted simultaneously because of crew time and space on the ISS. Therefore, studies addressing one risk may compete for flight resources with studies addressing another risk. For example, research projects for both the VIIP and Behavioral Health and Performance risks have been delayed for this reason, which in turn has caused slippage in the PRR schedule.

In January 2014, the President proposed extending the ISS through 2024 – a plan, which the Senate endorsed in a bill this year.¹¹ HRP management anticipates that extending ISS operations to 2024 will help NASA develop countermeasures to mitigate risks related to Team Performance, VIIP, and Unpredicted Effects of Medicine. Further, with the plan for a flexible path approach that involves cis-lunar habitation, the Agency has an opportunity to verify risk reduction strategies in space even after ISS operations end.

In addition, NASA needs to work through issues regarding researcher access to medical data already in the Agency's possession. NASA houses information from space flight experiments in its Life Sciences Data Archive, which includes data from 1961 (Mercury Project) through current flights, as well as analog studies involving human, plant, and animal subjects. In 2014, HRP surveyed its principal investigators and determined that 90 percent of those who sought archived data were able to access it.¹² However, only

¹¹ The Senate passed, S. 1297, "U.S. Commercial Space Launch Competitiveness Act," in August 2015, which states that NASA shall ensure that the ISS remains a viable and productive facility capable of potential U.S. utilization through at least FY 2024.

¹² 562 respondents completed the survey in 2014.

60 percent of respondents reported seeking such data. The top three reasons respondents gave for not seeking this data were (1) not needing the data, (2) not knowing how to request the data, and (3) not knowing what data was available. In addition, some investigators noted long lag times between their requests and receipt of data. According to HRP managers, a 2012 policy clarifying the process for requesting data has led to improvements, but they recognize data access remains a challenge for some researchers.¹³

Adequate research and testing facilities are also essential to timely development of countermeasures to address space travel risks. However, replicating the deep space environment in facilities on Earth or on the ISS is complicated. Although valuable insights can be gained from experiments carried out aboard the ISS, deep space presents a very different environment in terms of radiation, habitat size, and isolation from Earth. These differences make it difficult to correlate data collected on the ISS to the conditions of a deep space mission. For example, HRP examined the effects of radiation levels on the ISS on the nutrition and quality of food, and though they found no adverse effect, this may not hold true in the more intense radiation environment of deep space.

While ISS missions have defined vehicle and mission requirements, NASA has not established similar parameters for planetary missions. As the standing review panels have noted, planning an approach without defined mission requirements is difficult. For example, the current Mars DRM is based on a DRM from 2009, which NASA officials have stated will be updated in the future.

In addition, many key technologies required for human space flight to travel Mars have not yet been developed. For example, in 2012, the National Academies of Science noted the need for new propulsion technology and a habitat design. Similarly, NASA has noted that one way to mitigate risks associated with radiation, reduced gravity, and other conditions astronauts will experience during long duration, deep space travel is to develop propulsion systems that would reduce transit times. NASA technology development and design personnel stated that the Orion capsule currently under development is not suitable by itself for long duration missions and that a crew habitat of some type would be required. Several researchers we interviewed noted the difficulty in conducting research to mitigate risks associated with a mission for which there is no set spacecraft design or mission profile. Although NASA expects a spacecraft capable of transit to Mars will have less mass and volume than current vehicles, the vehicle's overall parameters remain unknown. Accordingly, it is unclear how much mass, volume, or weight will be available to accommodate potential countermeasures such as developing methods to supply food to a crew for up to 5 years without resupply. Options under consideration include shipping food ahead of time to a preexisting habitat and growing food in space; however, not knowing how much storage will be available in such a habitat or in a Mars-bound crew spacecraft complicates this challenge.

Finally, funding constraints have resulted in milestone delays so that HRP can prioritize research tasks. HRP management told us funding shortages and associated delays in research are not unusual, and that the program's approach is to rebalance funds in the middle of the fiscal year when they select research tasks to fund with grants. According to HRP management, HRP keeps about \$5 million in reserve to assist with budget needs that arise throughout the year. HEOMD has also contributed additional funds to HRP projects as needed. However, for FY 2015, these steps were not enough to offset a \$16 million shortage – about 10 percent less than the amount requested from Congress. As a result, HRP has had to delay start dates for multiple grants, including six to fund space radiation research.

¹³ Data Sharing Policy for Release of NASA Protected Health and Research Information, Space Life Sciences Directorate, March 2012.

NASA LACKS A COORDINATED APPROACH TO MANAGING ASTRONAUT HEALTH FOR LONG DURATION SPACE MISSIONS

NASA's management of crew health risks could benefit from increased efforts to integrate expertise from all related disciplines. While many life science specialists attempt to utilize the range of available expertise both inside and outside the Agency, NASA lacks a clear path for maximizing expertise and data at both the organizational and Agency level. For example, NASA has no formalized requirements for integrating human health and research among life sciences subject matter experts nor does it maintain a centralized point of coordination to identify key integration points for human health. Moreover, integrating the experiences of NASA's engineering and safety efforts would benefit the outside life sciences community. The lack of a coordinated, integrated, and strategic approach may result in more time consuming and costly efforts to develop countermeasures to the numerous human health and performance risks associated with deep space missions.

A Culture of Silos and the Absence of Agency-Level Integration

NASA has a long history of working in silos with technical teams collaborating primarily with specialists within their own fields. We found multiple examples of work taking place on health and human performance risks that suffered from such communication silos.

Presently at NASA, a board of experts comprised primarily of Agency life sciences managers and subject matter experts designates the various groups that approve and may oversee various projects. These boards meet on a routine basis to review risks, activities, documents, and other issues requiring management decisions. A level above that authority is the NASA Mission Directorate or Program officials, which are responsible for orchestrating the projects.¹⁴ At the project level, HHP life sciences subject matter experts typically collaborate with Agency experts from the safety and engineering technical authorities only during the development of operational hardware. At the board review level, engineering and safety technical authorities do not have permanent membership on life sciences boards and therefore HHP makes the initial identification of engineering and safety issues. At the Agency level, the life science community lacks a designated advocate to interface with the engineering, safety, and mission planning communities to ensure health and human performance issues are elevated and receive the appropriate attention across Agency disciplines.

¹⁴ Section 2.1.B Project Categorization and Section 2.4 Program and Project Oversight and Approval in NASA Procedural Requirements (NPR) 7120.5E, NASA Space Flight Program and Project Management Handbook. These sections define typical project categories and program and project oversight and approval.

The most prominent drivers of space vehicle architecture are the gravity environment, mission objectives and duration, size and number of crew, and limitations on mass and volume. According to NASA's Spaceflight Human System Standards, the human system should be viewed as an integral part of overall vehicle design. In other words, the standards of the human system should be centrally incorporated into vehicle design, mission architecture, countermeasures, and research. Several senior NASA officials we met with noted that although NASA has traditionally and successfully operated with a vehicle-centered design focus, a shift to a more human-centered design is necessary for Mars and other exploration class missions. While Agency officials agreed that a shift in the Agency's focus is required, they offered little insight into how NASA would effectively utilize human-centered design for long-term decision making in mission planning and vehicle design. However, many Agency officials pointed to astronaut input in the configuration of the Orion capsule in areas such as seating placement and lighting options.

NASA has been struggling to provide appropriate consideration of the human component in vehicle design for more than a decade. For example, as early as 2001, the IOM expressed the view that the Agency did not give the human component the attention it deserved:

NASA, because of its mission and history, has tended to be an insular organization dominated by traditional engineering, because of the engineering problems associated with early space endeavors, the historical approach to solving problems has been that of engineering. Long duration space travel will require a different approach, one requiring wider participation of those with expertise in divergent, emerging, and evolving fields.

NASA recognizes that the life sciences community may not be well integrated or using its resources as effectively as possible. For example, in July 2014, the Agency's Technical Capability Assessment Team recommended establishment of a life sciences technical capability position.¹⁵ According to the Team's report, such a capability would improve engagement among life sciences researchers by fostering collaborative dialog and knowledge exchange, enhancing communication among researchers, and providing advice to program and project managers. The recommended position has been established in the Office of the Chief Scientist at NASA Headquarters. However, the Team did not include medical operations and the human system integration work sponsored by HEOMD in this recommendation.

Both HHP and HRP are located at Johnson, the home Center for the astronaut crew office and all active astronauts, which facilitates the programs' operational and research tasks. Moreover, although HHP and HRP have distinct and separate functions, with HHP focusing primarily on current, human space flight mission operations and HRP on research for future deep space missions, HRP is largely dependent upon HHP for the majority of its research scientists, research facilities, and physical office space. Further, the majority of HRP staff are HHP employees who report to HHP management but are funded by programs other than HRP. Although the co-location and interdependencies between HHP and HRP should facilitate integration between the two groups, some stakeholders we spoke with expressed dismay at the lack of integration, collaboration, and productive communication between the two groups. For example, as discussed previously, NASA only recently identified vision impairment and changes in intracranial pressure as a serious risk to crew health. While changes in vision in some

¹⁵ NASA formed the Technical Capabilities Assessment to develop a more efficient operating model that maintains critical capabilities to meet current and future Agency mission needs.

crew members were noted for years through medical monitoring and believed to be temporary, it was only when permanent changes were noted in a few ISS astronauts that HRP experts and investigators identified a more substantial pattern in the historical data.

We also noted the lack of a formal process to facilitate integration between the life sciences research and operations communities. Instead, collaborative work occurs as a result of personal relationships. Moreover, for both HHP and HRP, the reporting of crew health risks for integration into other NASA programs at the Headquarters level is inadequate. During our discussions with key life sciences leaders, we anticipated that one official would claim responsibility for integrating ongoing life sciences work; however, this was not the case. Instead, many of the life sciences officials identified a need for a high-level focal point within HEOMD for all Agency issues related to astronaut health and the human system.

We found the lack of integration has led to confusion regarding the proper role of life sciences experts in developing technology for countermeasures. One of HRP's goals is to "develop and validate technologies that serve to characterize and reduce medical risks associated with human spaceflight" and the life sciences operational and research community at Johnson expects to develop much of the hardware to mitigate human health issues for current and future operations. However, HRP also conducts research "necessary to understand and reduce spaceflight human health and performance risks in support of exploration and enable development of human spaceflight medical and human performance standards." Tasking the same entity to both develop and validate technology rather than separating those roles across the Agency places the life sciences technology developer and the validator in potentially conflicting positions. Indeed, the appearance of a conflict of interest stemming from this dual role has been previously noted in dissenting opinions by Agency experts. When a life sciences researcher or hardware developer is also charged with validating or recommending the best available technology to the Agency, the appearance of favoring one's own technology is likely, regardless of whether or not undue favoritism exists. Moreover, representatives within NASA's engineering technology development areas expressed the view that HHP and HRP should be limited to developing enabling technology, such as an instrument developed to conduct research. Similarly, engineering hardware experts have expressed concern that these roles were not adequately separated within the life sciences communities. Nevertheless, the life sciences operational and research community at Johnson expects to develop much of their own hardware to mitigate human health issues, both for current and future operations. We are concerned by a lack of organizational clarity regarding technology development responsibilities for human system risk mitigation, particularly the lack of engagement of key NASA experts from outside the life sciences community.

Control Boards for Decision Making Lack Cross-Agency Expertise

NASA's HHP and HRP boards are not fully leveraging cross-Agency technical expertise and support from the safety and engineering communities. We found the boards did not consistently involve subject matter experts from across the NASA directorates when addressing human health and performance risks. Including engineering and safety and mission assurance experts on these boards could lead to improved mitigation responses and earlier incorporation and "buy-in" for mission and vehicle and habitat design planning.

HHP and HRP have a multi-level structure of control boards with key decision-making authority. The working level boards at Johnson have distinct yet complimentary roles meant to ensure necessary expertise and coverage within the HHP community. However, NASA experts from outside the life sciences discipline are not consistently included in the boards' work. For example, while HHP's Flight Activities Control Board has a permanent member from the engineering community, it has no representative from the safety and mission assurance community. Furthermore, most HHP control boards include experts from engineering and safety and mission assurance only as ad-hoc members to be called upon as determined by the life science experts.

In our judgment, it is important to include experts from both the engineering and safety community on these boards. Issues such as monitoring, countermeasure development, hardware selection, habitability, and performance needs all have inherent engineering and safety components. Without consistent participation by the safety and engineering technical authorities, HHP life sciences experts must identify safety and engineering issues themselves and decide when to call in experts from those areas. This can lead to delays in or failure to identify these issues. Inclusion of these technical communities on all HHP decision-making control boards would not only ensure participation of appropriate expertise from a cross section of the Agency's technical communities, but may help to identify crew health issues at an earlier juncture and avoid mistakes when planning countermeasures and developing technologies targeted at specific crew health risks.

We noted that at an August 2014 meeting, the HSRB discussed that owners of change requests need to do a better job ensuring that the correct evaluators, especially mandatory evaluators, are included in decisions relating to hardware changes and are given adequate time to respond to reviews. At the meeting, the HSRB Chair pointed out that HHP experts did not perform an engineering design review for microbiology hardware, which led the Chair to contact the experts during the meeting via telephone to get a real-time concurrence. In another instance, the development of hardware for an air quality replacement monitor did not receive timely input from engineering, which caused multiple approval delays and increased costs.

Historical Issues with Integration and Stove-piping

In 2002, both the engineering and human health and research communities recognized the need to build better working relationships and identify opportunities for integration. As a result, the directors of the Johnson Engineering Directorate and HHP signed a memorandum committing themselves to a "partnership whose purpose is to better position the organizations to achieve NASA's goals for human spaceflight and space research." The memorandum established agreements between the two organizations to provide space- and ground-based hardware and software that will better enable NASA to carry out its mission and required the formation of an Engineering and Science Review Board that would "authorize new joint products and processes to resolve significant issues and to approve joint positions and/or decisions for forwarding to NASA Headquarters or other external organizations." The memorandum appeared to be a blueprint to ensure long-term integration and allow both specialties to work together early in the project phase. Although the memorandum is still in effect, the Engineering and Science Review Board was never formed and to date working partnerships are not consistent within the Engineering Directorate and HHP. As a result, while integration issues were identified over a decade ago and initial corrective steps taken, the groups did not follow through to establish a formalized agreement of work.

The range of life sciences issues relevant to NASA missions are quite diverse and require a broad range of technical expertise. Accordingly, NASA has incorporated an extensive array of experts into its life sciences community to ensure full coverage across operational and research projects. However, we found that many of these experts, some of whom may also act as principal investigators for NASA research projects, operate in silos without a requirement to ensure diversified scientific teams that contain the appropriate portfolio of experts. This could lead to missed opportunities for collaborative efforts and a failure to recognize critical health issues in a timely manner. For example, one researcher we spoke with expressed the view that NASA may have identified the VIIP risk sooner had crew data been more effectively shared among life sciences experts.

NASA MUST ESTABLISH AND MAINTAIN AN ETHICAL FRAMEWORK FOR RISK ACCEPTANCE FOR LONG DURATION SPACE FLIGHT

Long duration missions will likely expose crews to health and human performance risks for which NASA has limited effective countermeasures. Accordingly, for these missions NASA will have to determine the level of risk that is acceptable and clearly communicate the Agency's decisions to astronauts, Congress, and the public. Moreover, NASA needs to continue to explore whether its current health care model for astronauts is sufficient to meet both the long-term health needs of the astronaut community and the research needs of the Agency.

Transparency of Risk Acceptance

For more than two decades, NASA has sought to understand the effects of space flight through the Longitudinal Study of Astronaut Health (LSAH), investigating a variety of issues relating to astronaut health both during and post mission. In addition, at NASA's request, the IOM has studied and issued reports on a variety of astronaut health issues and, in 2001, offered seven recommendations to improve NASA's medical care system and develop the infrastructure needed to support long duration missions. In 2004, the IOM recommended NASA improve the validity of the LSAH database and assume responsibility for the lifelong health care of its active and former astronauts. Finally, in 2014, the IOM issued a report that discussed expanding Agency policy for initiating and revising health standards, as well as, the related ethical principles and responsibilities OCHMO should incorporate into NASA's health and medical standards processes and decision-making. The report offered the following principles:

- *Avoid harm.* This principle includes the duty to prevent harm, exercise caution, and remove or mitigate harms that occur. Thus, NASA should exhaust all feasible measures to minimize the risks to astronauts from long duration and exploration space flights, including addressing uncertainties through approaches to risk prevention and mitigation that incorporate safety margins and include mechanisms for continuous learning that allow for incremental approaches to risk acceptance.
- *Beneficence.* This principle provides benefit to others. NASA should consider in its decision making the potential benefits of a specific mission, including its scientific and technological importance, as well as its potential beneficiaries such as current and future astronauts and members of society at large.
- *Favorable balance of risk and benefit.* This principle seeks both a favorable and acceptable balance between the risk of harm and potential for benefit. In authorizing long duration and exploration activities and in approving particular missions, NASA should systematically assess risks and benefits and the uncertainties attached to each, drawing on the totality of available scientific evidence, and ensuring that benefits sufficiently outweigh risks.

- *Respect for autonomy.* This principle ensures that individuals have both the right to self-determination and processes in place to exercise that right. NASA should ensure that astronauts are able to exercise voluntariness to the extent possible in personal decision making regarding participation in proposed missions, have all available information regarding the risks and benefits of the proposed mission, and continue to be apprised of any updates to risk and benefit information throughout the mission
- *Fairness.* This principle requires that equals be treated equally, burdens and benefits be distributed fairly, and fair processes be created and followed. NASA's decision making surrounding missions should explicitly address fairness, including the distribution of the risks and benefits of the mission, crew selection, and protections for astronauts after missions.
- *Fidelity.* This principle recognizes that individual sacrifices made for the benefit of society may give rise to societal duties in return. Given the risks that astronauts accept in participating in hazardous missions, NASA should respect the mutuality of obligations and ensure health care and protection for astronauts not only during the mission but after return, including provision of lifetime health care for astronauts.

The IOM's 2014 report also identified the following ethical "responsibilities" relating to and flowing from the ethical principles:

- Fully inform astronauts about the risks of long duration and exploration missions and make certain that the informed decision-making process is adequate and appropriate.
- Adhere to a continuous learning strategy, including health surveillance and data collection, to ensure that health standards evolve and improve over time and are informed by data gained before, during, and after long duration and exploration missions, as well as from other relevant sources.
- Solicit independent advice about any decision to allow any specific mission that fails to meet NASA health standards or any decision to modify health standards.
- Communicate with all relevant stakeholders such as astronauts and the public at large the rationale for, and possible impacts, including harm type, severity, and probability estimates, related to any decision about health standards in a procedurally transparent, fair and timely manner, and providing adequate opportunity for public engagement.
- Provide equal opportunity for participation in long duration and exploration missions to the fullest extent possible. For example, fairness in crew selection means that NASA should accept some group differences in population risk in order to create an equal opportunity to participate in missions, and accommodate individual variance from population-based risk estimates to the extent that individual differences do not jeopardize mission operations.
- Provide preventive long-term health screening and surveillance of astronauts and lifetime health care to protect their health, support ongoing evaluation of health standards, improve mission safety, and reduce risks for current and future astronauts.
- Develop and apply policies that appropriately and sufficiently protect the privacy and confidentiality of astronaut health data.

The IOM stated that if a human space flight mission cannot meet existing health standards or inadequate information exists to revise an existing standard, NASA's options are to: (1) expand current standards; (2) establish new, more permissive long duration and exploration health standards; or (3) grant an exception to the standard. The IOM found the first two options unacceptable when evaluated

against the ethical guidelines. Consequently, the IOM concluded that the only ethically acceptable option would be to make an exception to existing health standards. Additionally, the IOM recommended NASA consider exceptions only on a mission-by-mission basis and follow a strict ethics-based decision framework for determining whether waivers are appropriate for a particular mission. The IOM presented the following three-step decision-making process for NASA's consideration:

- *Level 1.* Whether and under what conditions are any missions that are unlikely to meet current health standards ethically acceptable.
- *Level 2.* Whether a specific, contemplated mission unlikely to meet current health standards is ethically acceptable.
- *Level 3.* Once a specific mission is deemed ethically acceptable, the crew is chosen based on the requisite skills and expertise needed and individual astronauts' health susceptibilities and personal risk factors, and their informed decision to participate.

An important component of risk acceptance the IOM identified is that NASA fully inform astronauts about mission risks and set up a process that ensures the astronauts have a full understanding of those risks before agreeing to participate. In addition, the IOM expressed the view that not all risks can be morally adjudicated by leaving the decision whether to accept them entirely to the astronauts. Rather, NASA has an independent responsibility to protect its employees and minimize risks to the extent possible. NASA has recognized this responsibility by requiring not only consent from participating astronauts but also that the responsible program, project, or operations manager formally accept increased levels of risks to human safety and formal concurrence from the responsible technical authorities.

Furthermore, the IOM stated that NASA communicate the true level of risk to Congress and the public. As the IOM pointed out in 2001:

The successes of the space program may have fostered the impression that space travel has few associated risks. Making potential problems and overall risks clear and openly disclosing them will allow NASA to gain continuing public understanding, trust, and support for exploration-class space missions. At the extreme, the public must be prepared for the possibility that all countermeasures may tragically fail, that a crew may not return from a prolonged mission, or that individuals may not be able to function physically or mentally upon their return.

NASA agreed with the IOM that making exceptions to health standards or going forward with a mission when health standards do not exist because of limited knowledge should occur only "under very limited circumstances" and stated that the Administrator would waive health standards only after careful assessment of the risk and benefits with the ethical principles. Currently, NASA is working to develop a detailed implementation plan that addresses each of the recommendations in the IOM's 2014 report.

Astronaut Health Care

NASA does not provide lifetime healthcare for spaceflight induced injuries or diseases that may develop once the astronauts leave the Agency. Currently, NASA provides comprehensive health exams to active astronauts to ensure they are "flight ready" and, once an astronaut retires, offers occupational surveillance screenings like blood chemistry panels and ocular assessments. However, beyond these services, retired astronauts are entitled only to the standard benefits provided to all Federal civil

servants and military personnel – benefits which themselves are tied to length of service and retirement age. Moreover, once astronauts retire NASA may lose access to their ongoing medical data that could help inform research regarding the effects of long-term space travel on human health.

In a series of reports over the past decade, the IOM has stressed NASA’s moral obligation to provide medical surveillance of and care to astronauts due to their occupational exposures. The IOM’s position is that NASA should develop a policy addressing the practical consequences that a career as an astronaut or the experience of space travel leaves individuals at increased risk for an adverse health effects. The IOM was particularly concerned in cases where the effects of space travel do not become obvious during or immediately after a space flight but develop only after the astronaut leaves active duty and is no longer receiving medical care from NASA. In the 2001 Safe Passages report, the IOM stated that it is essential that NASA create a comprehensive healthcare system for the dual purpose of maintaining astronaut health and collecting and analyzing data to inform future space travel. The IOM advocated for a system that would include care for all astronauts and their families.

According to NASA, approximately 70 percent of retired astronauts participate in NASA’s annual preventive screenings program. NASA officials told us that a comprehensive health care program would encourage more participation and provide the Agency with access to more comprehensive medical data that could help identify common issues sooner, which in turn could inform research and countermeasure development.

Providing health care to workers exposed to hazardous conditions is not unprecedented. For example, the Departments of Energy, Defense, and Veterans Affairs have programs for individuals exposed to beryllium, nuclear weapons tests, and Agent Orange.¹⁶ In each case, Congress passed legislation to ensure the Federal Government provides monitoring and medical care to affected civil servants and service members.

The 2005 NASA Authorization Act instructed the Administrator to “develop a plan to better understand the longitudinal health effects of space flight on humans” considering “the need for the establishment of a lifetime health care program for NASA astronauts and their families or other methods to obtain needed health data from astronauts and retired astronauts.” As part of this effort, NASA utilized a feasibility study conducted by the University of Nebraska Medical Center that estimated the cost of providing such care and identified three options using existing coverage platforms: (1) the existing Department of Defense program for military retirees and their dependents (Tricare), (2) private insurance, and (3) the Federal Employees Health Benefits Program. The cost of these options ranged from \$2.4 million to \$6.5 million per year for a population of 367 current and retired astronauts and their families. However, NASA determined it could not enact such a program without specific legislative authority. In 2010, NASA proposed legislation that would modify the Space Act to provide health insurance to all current and retired astronauts and their families, but the proposal gained little traction in Congress and was not enacted into law.

¹⁶ Beryllium is a hard, gray metal that occurs as a chemical component of certain rocks (bertrandite and beryl), coal and oil, soil, and volcanic dust. More than 90 percent of all beryllium was processed to produce nuclear weapons and workers exposed to beryllium dust are at risk of developing serious debilitating diseases. From 1962 to 1971, U.S. military forces sprayed more than 19 million gallons of herbicides over Vietnam to strip the thick jungle canopy that helped conceal opposition forces, destroy crops on which enemy forces might depend, and clear tall grass and bushes from around the perimeters of U.S. base camps. After a scientific report concluded that a contaminant in one of the primary chemicals used in the herbicide called Agent Orange could cause birth defects in laboratory animals, U.S. forces suspended its use.

Since 2010, the Agency has modified its proposed legislation to eliminate coverage for astronaut families, focusing instead on an occupational health care model for retired astronauts that mirrors other agencies' workers' compensation programs. The Agency's current proposal would utilize the existing infrastructure of the Lifetime Surveillance of Astronaut Health initiative and NASA processes for active astronaut occupational health care, focusing on early detection of health conditions using the Department of Labor Worker's Compensation program as the first approach to pay for treatment.

In the proposed NASA Authorization Act of 2015, Congress again instructed the Administration to prepare a response to the IOM's recommendations regarding lifetime health care for astronauts. The legislation requires NASA to report the estimated budgetary resources required for implementation of those recommendations and options that might be considered.

CONCLUSION

NASA has taken positive steps to address the human health and performance risks inherent in space travel. However, the Agency still faces significant challenges to ensuring the safety of crew members on a human mission to Mars or deep space. To that end, NASA must continue to develop countermeasures to minimize health and human performance risks and improve Agency insight into how much it will cost to do so and on what timetable. Moreover, effective mitigation of the risks to human health posed by long duration missions is a significant undertaking that can only be achieved with effective management and collaboration among the various NASA life sciences offices and technical experts from the engineering and safety disciplines. Accordingly, NASA must increase efforts to break down a culture of silos that impedes such collaboration.

NASA recognizes that the astronauts it sends on deep space missions will be exposed to a greater level of risk than the Agency accepts for current missions to low Earth orbit. Therefore, it is crucial NASA develop an ethical framework to guide the informed consent and waiver process for astronauts. In addition, NASA must be transparent with Congress and the public about the level of the risk involved in deep space missions. Finally, NASA should continue to consider whether its current model for astronaut health care meets its research needs and the health care needs of the astronaut community.

RECOMMENDATIONS, MANAGEMENT'S RESPONSE, AND OUR EVALUATION

In order to ensure NASA management has the best possible information available to make decisions related to human health and performance risks to Agency missions, we recommended the Manager of HRP in coordination with HSRB

1. ensure HRP costs for research and countermeasure development are accurate so the program can be better informed on how funding challenges will impact the rate of progress for countermeasure development and
2. ensure the PRR accurately reflects the status of research and realistic timeframes for countermeasure development to better determine what risks will be mitigated for the first human mission to Mars.

In order to ensure appropriate integration of Agency expertise across disciplines, we recommended the Associate Administrator for HEOMD

3. establish a primary point of coordination within HEOMD to interface with all NASA programs, projects, and functions to ensure human health and performance issues have appropriate visibility;
4. ensure that integration of technical authorities is occurring and consider inclusion of engineering and safety experts on all HHP and HRP control boards; and
5. clarify the organizational technology development responsibilities for human system risk mitigation.

Regarding astronaut health care, we recommended the NASA Administrator and the Chief Health and Medical Officer

6. determine whether the current model satisfies Agency needs and the needs of the astronaut community and, if not, pursue any necessary legislative authority to implement necessary changes.

We provided a draft of this report to NASA management, who concurred or partially concurred with our recommendations and described planned corrective actions. Because we consider management's comments responsive to our recommendations, the recommendations are resolved. We will close the recommendations upon completion and verification of the proposed corrective actions. Management's full response to our report is reproduced in Appendix C. Technical comments provided by management have also been incorporated, as appropriate.

Major contributors to this report include, Laura Nicolosi, Mission Support Director; Julia Eggert, Project Manager; Scott Riegenbach, Team Lead; Noreen Khan-Mayberry, Ph.D., Technical Evaluator; Rebecca Wilson, Management Analyst; and Jason Hensley, Auditor.

If you have questions about this report or wish to comment on the quality or usefulness of this report, contact Laurence Hawkins, Audit Operations and Quality Assurance Director, at 202-358-1543 or laurence.b.hawkins@nasa.gov.

Handwritten signature of Paul K. Martin in black ink.

Paul K. Martin
Inspector General

APPENDIX A: SCOPE AND METHODOLOGY

We performed this audit from April 2014 through September 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

This review assessed NASA's efforts to manage human health and performance risks for space exploration. We reviewed Federal and NASA policies, regulations, and plans to determine the requirements and criteria for managing human health and performance risks. The documents we reviewed included:

- NASA-STD-3001, Vol. 1, "NASA Spaceflight Human System Standard Volume 1: Crew Health," March 2007
- NASA-STD-3001, Vol. 2, "NASA Spaceflight Human System Standard Volume 2: Human Factors, Habitability, and Environmental Health," January 2011
- NASA Policy Directive 8900.5B, "NASA Health and Medical Policy for Space Exploration," December 2011
- NPR 7120.5E, "NASA Space Flight Program and Project Management Handbook," August 2012.
- NPR 7120.8, "NASA Research and Technology Program and Project Management Requirements," April 2013
- NPR 7120.11, "NASA Health and Medical Technical Authority (HMTA) Implementation," November 2011
- NPR 8000.4A, "Agency Risk Management Procedural Requirements," January 2014
- NPR 8900.1A, "NASA Health and Medical Requirements for Human Space Exploration," July 2012
- 14 Code of Federal Regulation 1230, "Protection of Human Subjects," January 2012
- 45 Code of Federal Regulation 46, "Protection of Human Research Subjects," October 2013

To determine how NASA manages risk mitigation, we reviewed the status of NASA's 30 human health and performance risks, of which 23 and 2 concerns are assigned to HRP, based on the program's schedule and risk matrix. We then selected four risk areas to better understand management and identify challenges. The four risk areas were (1) Behavioral Health and Performance, (2) Inadequate Food and Nutrition, (3) Space Radiation, and (4) VIIP. We reviewed Evidence Reports, integrated research plans, budgets, schedules, HRP's annual reports, external reviews, and information on DRMs. Additionally, we interviewed numerous individuals to gain an understanding of how health and human performance risks are currently managed and integrated across the Agency, including representatives from the HEOMD, HHP, HRP, OCHMO, various subject matter experts, and a selection of astronauts.

Use of Computer-Processed Data

We did not use computer-processed data to perform this audit.

Review of Internal Controls

We evaluated internal controls, including NASA policies and procedures associated with the audit objectives, and concluded that the internal controls were generally adequate, except in specific circumstances, as discussed in the body of this report. Our recommendations, if implemented, should correct the weakness identified.

Prior Coverage

During the last 5 years, the NASA Office of Inspector General and IOM have issued four and three reports, respectively, of significant relevance to the subject of this report. Unrestricted OIG reports can be accessed at <http://oig.nasa.gov/audits/reports/FY16>.

NASA Office of Inspector General

NASA's Efforts to Maximize Research on the International Space Station (IG-13-019, July 8, 2013)

A Review of NASA's Replacement of Radiation Monitoring Equipment on the International Space Station (IG-11-027, September 29, 2011)

NASA's Astronaut Corps: Status of Corrective Actions Related to Health Care Activities (IG-10-016, July 6, 2010)

NASA's Constellation Standing Review Boards Established without Due Regard for Member Independence Requirements (IG-09-011, February 25, 2009)

Institute of Medicine

Health Standards for Long Duration and Exploration Spaceflight: Ethics Principles, Responsibilities, and Decision Framework (2014)

Review of NASA's Longitudinal Study of Astronaut Health (2004)

Safe Passage: Astronaut Care for Exploration Missions (2001)

APPENDIX B: ACCEPTANCE OF HUMAN HEALTH AND PERFORMANCE RISKS BY SELECTED DRMs

Risk	Risk Summary	Low-Earth Orbit (6 months)	Low-Earth Orbit (1 year)	Lunar Visit Habitation (1 year)	Planetary (e.g. Mars) (3 years)
Acute and Chronic Carbon Dioxide (CO2)	Given carbon dioxide levels in spacecrafts are 6-20 times higher than on Earth, exposure may impact crew health and performance when complex decisions are necessary.				
Adverse Behavioral Conditions (Bmed) ^a	Isolated, confined environments can lead to adverse behavioral conditions and mental disorders				
Altered Immune Response (Immune) ^a	Changes in immune function can result in reactivation of latent herpes-viruses, rashes and hypersensitivity reactions				
Bone Fracture (Fracture) ^a	Adverse changes in bone strength may result in fractures and early onset of osteoporosis				
Cardiac Rhythm Problems (Arrhythmia) ^a	Micro-gravity, radiation, stress, and fluid shifts can result in cardiac rhythm disturbances				
Celestial Dust Exposure (Dust) ^a	Celestial dust and volatiles (lunar, Mars, and asteroids) can lead to damage to the respiratory, cardiopulmonary, ocular and dermal systems				
Decompression Sickness (DCS) ^a	Given that tissue inert gas partial pressure is often greater than ambient pressure during phases of a mission (primarily EVA), there is a possibility of decompression sickness (DCS)				
Electrical Shock (Shock)	Electrical systems on spacecraft have the potential to release an electrical shock from both direct contact and plasma				

A - Accepted
 RM - Requires Mitigation
 TBD- To Be Determined
 N/A - Not Applicable



Very low to low consequences
 Low to medium consequences
 High consequences

Note a: Risk considered to be a Human Research Program (HRP) risk.

Note b: HMTA and HRP consider issue to be a concern and have not formally accepted it as a risk.

Risk	Risk Summary	Low-Earth Orbit (6 months)	Low-Earth Orbit (1 year)	Lunar Visit Habitation (1 year)	Planetary (e.g. Mars) (3 years)
Exploration Atmospheres (ExAtm) ^a	Changes in atmosphere pressure when engaging in or finishing EVA can lead to mild hypobaric hypoxia	RM / RM	RM / RM	RM / RM	RM / RM
Hearing Loss (Hearing)	Given conditions during spaceflight (e.g. noise and physiological changes), crew auditory systems could experience temporary or permanent reductions in hearing sensitivity	A / A	A / A	A / A	A / A
Human-System Interaction Design (HSID) ^a	Training, procedures, human-robotic and human-computer interactions and vehicle, habitat and workplace design integration effect efficiencies and injuries	A / A	A / A	RM / A	RM / A
Host-Microorganism Interactions (Micro-host) ^a	The combination of increased microbe virulence and compromised immunity can increase illnesses	A / A	A / A	A / A	RM / RM
In-flight Medical Capabilities (ExMC) ^a	Limited medical capabilities can result in in-flight medical events leading to unacceptable health and mission outcomes	A / A	A / A	RM / RM	RM / RM
Inadequate Nutrition and Food Storage (Nutrition, Food) ^a	Inadequate nutrition and food storage can compromise crew health (e.g. bone mass and strength, endurance, cardio-, gastro-, and endocrine function)	A / A	A / A	A / A	RM / RM
Inadequate Team Performance (Team) ^a	Performance and behavioral health decrements due to inadequate cooperation, coordination, communication, and psychosocial adaption with team during spaceflight	A / A	A / A	A / A	RM / A
Injury, Compromised Performance Due to EVA Operations (EVA) ^a	Inadequate EVA Suit Systems can result in injuries which compromise EVA performance and crew health	A / A	A / A	RM / RM	RM / RM
Intervertebral Disc Damage (IVD) ^b	The lengthening of the spine in micro-gravity may lead to intervertebral disc damage when re-exposed to gravity	TBD / TBD	TBD / TBD	TBD / TBD	TBD / TBD
Occupant Protection (OP) ^a	The dynamic loads from launching and landing can result in crew injury	A / A	A / A	RM / RM	RM / RM

A - Accepted
 RM - Requires Mitigation
 TBD- To Be Determined
 N/A - Not Applicable



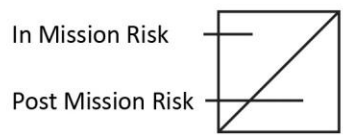
Very low to low consequences
 Low to medium consequences
 High consequences

Note a: Risk considered to be a Human Research Program (HRP) risk.

Note b: HMTA and HRP consider issue to be a concern and have not formally accepted it as a risk.

Risk	Risk Summary	Low-Earth Orbit (6 months)	Low-Earth Orbit (1 year)	Lunar Visit Habitation (1 year)	Planetary (e.g. Mars) (3 years)
Orthostatic Intolerance (OI) ^a	Re-exposure to Earth and gravity can result in loss of blood pressure and fainting	A	A	A	A
Pharmacokinetics (PK/PD) ^b	The body may handle administered medications, the concentration of circulating medication, differently in the spaceflight environment	TBD	TBD	TBD	TBD
Reduced Aerobic Capacity (Aerobic) ^a	Exposure to a micro-gravity environment causes cardiovascular fitness to decline	A	A	A	RM
Reduced Muscle Mass, Strength and Endurance (Muscle) ^a	Muscle mass, strength and endurance can decline during spaceflight	A	A	A	RM
Renal Stone Formation (Renal) ^a	Renal (kidney) stone formation may lead to urinary calculi or urolithiasis, pain, nausea, vomiting, hematuria, infection and/or hydronephrosis	A	A	A	RM
Sensorimotor Alterations (Sensorimotor) ^a	Gravitational transitions can effect eye-hand, balance and locomotor coordination which would impair control of spacecraft	A	A	RM	RM
Sleep Loss/Work Overload (Sleep) ^a	Performance errors and adverse health outcomes due to fatigue resulting from sleep loss, circadian desynchronization, and work overload	A	A	A	RM
Space Adaptation Back Pain (SABP)	Given the physiological changes in spaceflight, crewmembers may experience space adaptation back pain ranging from aches and stiffness to tingling and numbness or radicular pain.	TBD	TBD	TBD	TBD
Space Radiation Exposure (Radiation) ^a	Radiation exposure can increase cancer morbidity/mortality and result in degenerative tissue and central nervous system damage and acute radiation sickness	A	A	RM	RM
Sunlight Exposure (Sunlight)	Exposure to solar light during spaceflight missions may lead to crewmembers developing solar retinopathy, photokeratis and/or sunburn	A	A	A	A

A - Accepted
 RM - Requires Mitigation
 TBD- To Be Determined
 N/A - Not Applicable



Very low to low consequences
 Low to medium consequences
 High consequences

Note a: Risk considered to be a Human Research Program (HRP) risk.

Note b: HMTA and HRP consider issue to be a concern and have not formally accepted it as a risk.

Risk	Risk Summary	Low-Earth Orbit (6 months)	Low-Earth Orbit (1 year)	Lunar Visit Habitation (1 year)	Planetary (e.g. Mars) (3 years)
Toxic Exposure (Toxic)	Various sources of toxic exposures cannot be eliminated during missions, as a result there is a possibility that exposure will cause illness to the crew				
Urinary Retention	Physiological changes, altered gravity, and limited access to voiding may result in some crew developing urinary retention				
Unpredicted Medication Effects (Stability) ^a	Given the hostile space environment, the ability to treat medical conditions with pharmaceuticals may be significantly reduced				
Vision Impairments and Intracranial Pressure (VIIP) ^a	Changes in vision and intracranial pressure could result from fluid shifts due to changes in gravity				

A - Accepted			Very low to low consequences
RM - Requires Mitigation			Low to medium consequences
TBD- To Be Determined			High consequences
N/A - Not Applicable			

Note a: Risk considered to be a Human Research Program (HRP) risk.

Note b: HMTA and HRP consider issue to be a concern and have not formally accepted it as a risk.

APPENDIX C: MANAGEMENT'S COMMENTS

National Aeronautics and Space Administration
Headquarters
 Washington, DC 20546-0001



October 28, 2015

Reply to Attn of:

Human Exploration and Operations Mission Directorate

TO: Assistant Inspector General for Audits

FROM: Associate Administrator for Human Exploration and Operations
 Chief Health and Medical Officer

SUBJECT: Response to Office of Inspector General (OIG) Draft Audit Report, "NASA's Efforts to Manage Health and Human Performance Risks for Space Exploration" (A-14-011-00)

The Human Exploration and Operations Mission Directorate (HEOMD) and the Office of the Chief Health and Medical Officer (OCHMO) appreciate the opportunity to review your draft report entitled "NASA's Efforts to Manage Health and Human Performance Risks for Space Exploration" (A-14-011-00).

The successful mitigation of human system risks for space flight is essential for NASA to conduct long-duration space missions in and beyond low-Earth orbit (LEO). This mitigation approach requires the integration of human health and performance, engineering, mission management, and policy disciplines to enable the safe conduct of human space flight missions and the protection of the long-term health of astronauts. HEOMD, OCHMO, and the Human Health and Performance Directorate (HHPD) at the Johnson Space Center (JSC) have worked diligently for the past decade to achieve an integrated approach to human health in space that incorporates the human system into spacecraft design and operations, following an occupational health model, as recommended by the National Academies of Science, Engineering, and Medicine. The Health and Medical Technical Authority has promulgated health standards and evidenced-based risk management, which address integrated space health risks that drive spacecraft design as well as the Human Research Program's (HRP) research and development (R&D) priorities and investments. We appreciate your review and the opportunity it affords us to improve our human research and health care system.

In the report, the OIG makes six recommendations intended to ensure the successful mitigation of human system risks for space flight. NASA has been working in all of these areas for some time. Thus, the report represents a validation of, rather than a correction to, NASA's HHP plans and the challenges ahead. Our concurrence indicates our intent to continue these efforts.

NASA's responses to the OIG's recommendations, including planned corrective actions follow:

In order to ensure NASA management has the best possible information available to make decisions related to human health and performance risks to Agency missions, the OIG recommends the Manager of HRP in coordination with the Human System Risk Board (HSRB):

Recommendation 1: Ensure HRP costs for research and countermeasure development are accurate so the program can be better informed on how funding challenges will impact the rate of progress for countermeasure development.

Management's Response: Concur. HRP presents to HEOMD, annually, a breakdown of its R&D investments by risk for the coming fiscal year, as well as a revised integrated Path to Risk Reduction (PRR) chart based on the prior year's new evidence (see Recommendation 2 response). Throughout that execution year, HRP conducts quarterly technical, cost, and schedule reviews of all its supporting elements, and it reports the outcomes of those reviews to HEOMD at the Directorate Program Management Council (DPMC) meetings. However, HRP does not normally reassess its R&D investments by risk during the execution year. Beginning in FY16Q1, HRP will add this assessment to its standard quarterly DPMC briefing.

Estimated Completion Date: March 1, 2016

Recommendation 2: Ensure the HRP Path to Risk Reduction (PRR) accurately reflects the status of research and realistic timeframes for countermeasure development to better determine what risks will be mitigated for the first human mission to Mars.

Management's Response: Concur. HRP conducts quarterly technical, cost, and schedule reviews of all its supporting elements. Any changes in the PRR identified during that quarter are reported to HEOMD as schedule shifts at the following DPMC meeting. All changes to the PRR are reviewed and baselined at least annually by the Human Research Program Control Board and a new version of the PRR is issued following the review. The Microsoft Project scheduling tool implemented by HRP during FY15 provides increased confidence in the reliability of its PRR schedules and informs cross-risk effects that were previously difficult to track. This year, HRP will begin implementing NASA best practices for project scheduling as well as the NASA Schedule Test and Assessment Toll (STAT) for schedule logic analysis to ensure that the PRR reflects the most accurate estimates possible for its risk-by-risk R&D efforts.

Estimated Completion Date: March 1, 2016

In order to ensure appropriate integration of Agency expertise across disciplines, the OIG recommends that the Associate Administrator for HEOMD:

Recommendation 3: Establish a primary point of contact within HEOMD to interface with all NASA programs, projects, and functions to ensure human health and performance issues have appropriate visibility.

Management's Response: Partially concur. Coordination among the involved organizations, programs, and technical authorities is frequent and productive. NASA will convene stakeholders in the human system (OCHMO, Life Sciences Capability Leader in the Office of the Chief Scientist, responsible divisions and Programs in HEOMD, Human Health and Performance Directorate at JSC, and the Space Technology Mission Directorate (STMD) to develop and implement a comprehensive plan to enhance the visibility of human health and performance issues in the relevant Agency decision-making forums.

Estimated Completion Date: May 2, 2016

Recommendation 4: Ensure that integration of technical authorities is occurring and consider inclusion of engineering and safety experts on all HHP and HRP control boards.

Management's Response: Concur. The HSRB will continue annual reviews of human system risks that integrate subject matter expertise across many disciplines. In addition, subject matter expertise from the Engineering Technical Authority (ETA) and Safety & Mission Assurance Technical Authority (SMTA) will be added to the HH&P Flight Activities Control Board (FACB) and HRSB. HRP development ends at Technology Readiness Levels (TRL) 6-7, after which the target flight programs take over, employing their extant technical authority representatives. HRP is discussing with representatives from the ETA and SMTA the proper use of Technical Authority experts in its TRL 1-6 activities. It will formalize in its program documentation and practice the approaches they recommend.

Estimated Completion Date: May 2, 2016

Recommendation 5: Clarify the organizational technology development responsibilities for human system risk mitigation.

Management's Response: NASA concurs with this recommendation. NASA will ensure that a plan is developed to clarify organizational responsibilities for technology development as part of its response to recommendation # 3. In addition, HRP is charged via its Program Commitment Agreement with developing to TRL 6-7 any risk mitigation tools or countermeasures hardware necessary to mitigate the risks in its R&D portfolio. Beyond this, HRP's customers, the flight development programs, assume responsibility for flight hardware development (or transition to operations). HRP will update its program documentation to reflect its continued

engagement of representatives from space medicine operations, the crew office, current flight development programs, Advanced Exploration Systems (AES), and STMD. It will also continue to employ Customer Supplier Agreements to ensure the operational communities are aware of HRP efforts and transition plans.

Estimated Completion Date: September 30, 2016

Regarding astronaut health care, the OIG recommends the NASA Administrator and the Office of the Chief Health and Medical Officer:

Recommendation 6: Determine whether the current model satisfies Agency needs and the needs of the astronaut community and, if not, pursue any necessary legislative authority to implement necessary changes.

Management's Response: Concur. The concept of providing long-term astronaut health care has also been supported and urged by NASA external advisory groups for a number of years. For approximately 10 years, OCHMO and the HEOMD, with the full support of NASA senior management, have pursued legislative authority to do so. While a number of plans that would provide both a system for managing space flight-related health issues for retired astronauts and a mechanism for collecting follow-up medical data on this unique population have been submitted to the legislative process, to date, none has been approved by the Congress which must grant NASA the authority to implement such a system.

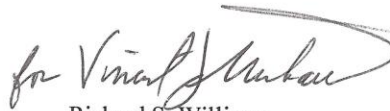
Estimated Completion Date: Language to authorize NASA to provide long-term health care of astronauts will again be submitted at the next opportunity for submitting legislative language.

We have reviewed the draft report for information that we believe should not be publicly released. We have not communicated any concerns regarding the public release of information contained in your report.

Again, thank you for the opportunity to review and comment on the subject draft report. If you have any questions or require additional information regarding this response, please contact Michelle Bascoe at (202) 358-1574.



William H. Gerstenmaier



Richard S. Williams

APPENDIX D: REPORT DISTRIBUTION

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(Assignment No. A-14-011-00)