MEDICAL AND HEALTH POLICY FORMULATION FOR HUMAN EXPLORATION OF THE SOLAR SYSTEM

Part II: Health and Medical Care Policies and Practices in Allocating Resources for Human Space Exploration
March 30, 2006

Prepared by the Office of International Medical Policy School of Public Policy George Mason University
We shall not cease from exploration
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time.

*The last four Quartets in the Little Gidding, 1942*

*By*

*T.S.Eliot*

This image was obtained by the Mars Surveyor on May 8, 2003, and shows the view of the Earth and Moon as they would appear from Mars. The shot captured the view of the Americas and a cloud cover over the northern hemisphere.
Dedication

Dedicated to the memory of our colleague and mentor Dr. John Zapp, whose support and encouragement made this research endeavor possible.
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TABLE OF CONTENTS

DEDICATION ................................................................................................................... 3

RESEARCH TEAM ........................................................................................................ 4

ACKNOWLEDGEMENTS ............................................................................................... 5

THE OFFICE OF INTERNATIONAL MEDICAL POLICY ............................................ 7

SUMMARY ....................................................................................................................... 8

INTRODUCTION ........................................................................................................... 12

  The Challenge ............................................................................................................ 13

  Resources And Risks ............................................................................................... 16

METHODOLOGY AND APPROACH ........................................................................ 18

DISCUSSION .................................................................................................................. 19

CONCLUSIONS ............................................................................................................. 24

REFERENCES ................................................................................................................ 29

ATTACHMENT I: HEALTH AND MEDICAL CARE POLICIES AND PRACTICES IN ALLOCATING RESOURCES FOR HUMAN SPACE EXPLORATION PARTICIPANT LIST ................................................................. 31

ATTACHMENT II: HUMAN HEALTH AND MEDICAL DIRECTION FOR SPACE EXPLORATION ....................................................................................................................... 33
The Office of International Medical Policy (http://policy.gmu.edu/oimp/)

The mission of the Office of International Medical Policy is to provide a health and medical policy focus for the School of Public Policy and to facilitate interdisciplinary and international research and training activities within and outside the George Mason University.

The George Mason University School of Public Policy (GMU/SPP) emphasizes interdisciplinary and alternative approaches to public policy. In addition to offering seven master's degrees and the largest Ph.D. program in Public Policy in the Nation, SPP maintains a variety of hands-on research activities conducted through several research centers. From global issues, such as peacekeeping and electronic commerce, to regional issues, such as land use and transportation management in Northern Virginia, SPP is an important academic institution for inquiry into public policy formulation and development of innovative solutions.

Established by SPP in 2004, the Office of International Medical Policy (OIMP) provides leadership and focus for the study and teaching of global medical and public health practices and policies. From its inception, OIMP was intended to complement and enhance the SPP training and research portfolio. OIMP emphasizes academic studies into global health challenges, interdependencies, and security.
Summary

A little over 200 years ago in his letter to Meriwether Lewis on June 20, 1803, President Thomas Jefferson expressed his care and concern for human life and safety:

“...To your own discretion therefore must be left to the degree of danger you may risk, and the point at which you should decline, only saying we wish you to err on the side of your safety, and to bring back your party safe even if it be with less information...”.

Though plagued with many diseases, foreseen and unknown, the expedition returned safely with only one life lost and a wealth of novel knowledge of the American West. This historic accomplishment is a tribute to the expedition leadership, foresight, and medical preparations. Thomas Jefferson’s preoccupation with human welfare should continue to inspire and guide future undertakings into the unknown environments, especially space.

This report addresses policies and practices governing the resource allocation process for health and medical systems in the design, development, and mission operations of human exploration of space. In the preparation of this report, the research team sampled National Aeronautics and Space Administration (NASA) practices, reviewed relevant experiences, and extracted lessons applicable to future human space exploration endeavors. Private sector investment in human space exploration is still in its infancy and was not addressed in this report. It is expected that some of the findings contained in this report might benefit future privately supported human space activities, notably space tourism, beyond suborbital flight.

Space-faring nations should attempt to mitigate space exploration risks by carefully addressing the hazards and their long-term consequences. Hazards that astronauts face during space travel are *internal* (biomedical or vehicular), *external* (meteorites or radiation), and *systemic* (the result of a cascade of events). Medical risk analysis relies on databases that are developed from research protocols carried out in ground-based, space flight, and post-flight studies. Risk analysis should be a sustained undertaking, since new information about various obstacles astronauts are facing in space is received continuously. Risk assessment must be done by methods that include probabilistic analysis and worst case scenarios. As we continue to plan for future Moon landings and beyond, an inescapable conclusion that emerges from the analysis of affordability is the need to acquire resources by living off the land. The ability to create fuel and oxidizer for the return journey and surface operations, as well as water and oxygen for life support, should be part of the occupational health program design for future space explorers. Choices of propulsion, habitat design, and mission operations will invariably affect the design of medical systems and protection of the health of future astronauts. Concepts for establishment of a *space occupational health practice* should be addressed as soon as possible.

Technology requirements for health, safety, productivity, and affordability stiffen even more as we progress to more complex distant missions or to a permanent settlement on
the Moon or Mars. Planning for future missions raises many questions that require solutions, such as:

- How long should an interplanetary crew depend on Earth’s support?
- How long will and can humans be productive in one-third or one-sixth gravity?
- Can we adequately protect our crews and supply them with a closed-loop life support system?
- What do we take with us, and what do we leave behind?
- What will be the long-term physiological and biological implications to humans living away from Earth?

This is just a sample of complex issues to be addressed and by no means represents an exhaustive list of questions. A sustained effort by the government and academia to bring together interdisciplinary teams over a period of time to predict and address such concerns will be required.

The space flight environment poses many challenges to human health and survival. The combined technological-biological acclimatization must be maintained and controlled. The potential implications and side effects of any countermeasures to altered gravity changes must be recognized. A coherent long-term strategy to develop such a body of exploration knowledge remains unarticulated, but is nevertheless required to prepare us for the future. We need only to look back at the ill-fated Sir John Franklin Expedition that used untested technology, or the early Nordic and Spanish settlements of North America that relied on the re-supply from the home base, to see the consequences of ambiguous planning. In many instances, the exploration needs will outstrip the technological resources. Conversely, novel technology might take years of development and testing and can be too complex or cost prohibitive to be of use.

Thus available technologies should be incorporated into the design of new space vehicles when preparing for the relatively short duration missions to the Moon. The design of the transports and habitats should allocate adequate resources to:

- Environmental Health
- Preventive Medicine
- Rehabilitation
- Medical and Surgical Care

Medical care should be tailored to anticipate crew health risks, be responsive to expedition-unique medical risks, and provide for the use of Advanced Directives.

Prior to incorporation into the mission architecture, risks presented by the explorers’ skills and constrained capabilities should be addressed. Some of these risks are associated with resource provision, logistics, and availability, scientific and experience-based knowledge, and, limitations of the expedition capabilities (people, technology, and systems) stemming from self-imposed mission constraints.
Anticipation and prevention of technologically induced side effects and/or injuries will reduce the burden on the health care system. The principle of “do it right the first time” saves resources, is cost effective and should be incorporated into the decision process leading to health and medical resource allocations. Not all injuries and illnesses will be treatable, considering the limited availability of medical resources during the course of the journey. Finally, the relative rank of the health and medical concerns within the NASA’s global risk prioritization schemes for human space missions should be established.

Maintaining environmental health and preventing degradation of the environment should be the highest priority for ensuring mission success. Identifying health risk and removing those risks through preventive care, countermeasures, and potential selection of individuals free of conditions that can be aggravated during the mission should be given thorough consideration. These measures are especially important if the spacecraft and habitat systems cannot guarantee full protection. Finally, based on the most probable assessment of the potential medical event, a specially tailored medical care system should be provided. Medical training should be developed early and in parallel with health care requirements on a mission. Additional considerations should be given to the already deployed and available resources at the mission destination. For example, most health and medical care resources should be available during the inbound and resident time of the mission phases for missions destined to land on the surface of the Moon or Mars. The return phase might not require as many health care resources given the presence of the medical infrastructure on Earth.

One of the major national and international assets created by NASA is the Longitudinal Study of Astronaut Health (LSAH), which is currently underway. Biomedical data is collected from astronauts throughout their life cycle. This study was initiated in 1976 and already has produced information that is being incorporated into the planning for future space missions. Unfortunately, there is not 100% compliance with this study, partly because there is a lack of incentive for continued participation by individuals who move away from the NASA Lyndon B. Johnson Space Center. One way to increase participations is to provide an astronaut health care for life program for the astronauts and their immediate family, which will ensure standardized care, medical data collection, and generational follow up. Once successfully designed and implemented, such a program would enhance the understanding of how humans can travel safely and live longer in space, enhance the space medicine knowledge base, serve as a model for other space-faring nations, and contribute to the codification and standardization of the international space medicine programs. Astronaut health care for life should be part of the national legislation process to provide a comprehensive health insurance program for the U.S. astronauts and their dependents (17).

The research team proposed a risk assessment model and a priority ranking of the health and medical needs for all exploration missions regardless of destination. Maintenance of life support integrity and preventive care practices should be at the core of all space exploration planning. Reliance on medical care should not be a primary line of practice in the space medicine settings since the medical care delivery will be limited by the severity
of the illness or injury, resources available, and, especially, the training, skills and proficiency of the astronauts.
Introduction

Excerpts of the President’s Vision are presented below:

“…….Our first goal is to complete the International Space Station by 2010. We will finish what we have started; we will meet our obligations to our 15 international partners on this project. We will focus our future research aboard the station on the long-term effects of space travel on human biology. The environment of space is hostile to human beings. Radiation and weightlessness pose dangers to human health, and we have much to learn about their long-term effects before human crews can venture through the vast voids of space for months at a time. Research on board the station and here on Earth will help us better understand and overcome the obstacles that limit exploration. Through these efforts we will develop the skills and techniques necessary to sustain further space exploration……

…….Our second goal is to develop and test a new spacecraft, the Crew Exploration Vehicle, by 2008, and to conduct the first manned mission no later than 2014. The Crew Exploration Vehicle will be capable of ferrying astronauts and scientists to the Space Station after the shuttle is retired. But the main purpose of this spacecraft will be to carry astronauts beyond our orbit to other worlds. This will be the first spacecraft of its kind since the Apollo Command Module.

…….Our third goal is to return to the moon by 2020, as the launching point for missions beyond. Beginning no later than 2008, we will send a series of robotic missions to the lunar surface to research and prepare for future human exploration. Using the Crew Exploration Vehicle, we will undertake extended human missions to the moon as early as 2015, with the goal of living and working there for increasingly extended periods……

Returning to the moon is an important step for our space program. Establishing an extended human presence on the moon could vastly reduce the costs of further space exploration, making possible ever more ambitious missions. With the experience and knowledge gained on the moon, we will then be ready to take the next steps of space exploration: human missions to Mars and to worlds beyond…”

On January 14, 2004, President George W. Bush, in his speech at NASA Headquarters in Washington, D.C., presented his vision for the space exploration program. The “Renewed Spirit of Discovery: the President’s Vision for the U.S. Space Exploration” set the stage for moving NASA human space flight away from the Low Earth Orbit (LEO) and into the Solar System. The Vision expanded on the human health, well-being, and safety.

In response to the Vision, NASA proceeded with the development of a strategy for the design and acquisition of a new set of space transportation systems. These new space vehicles would allow NASA to travel to different destinations for “places for humans to go, live, work, conduct scientific enquiry and ultimately settle in our Solar System” (1).

On September 19, 2005, NASA unveiled its plan to return to the moon by 2018. The architecture presented was the result of extensive research and planning by the Exploration Systems Architecture Study (ESAS). The Crew Exploration Vehicle (CEV) will be a larger version of the Apollo capsule, designed to carry six people to the International Space Station (ISS) and four on lunar missions. It will be launched on the Crew Launch Vehicle (CLV) based on Shuttle technology. A second stage will place the CEV in low Earth orbit for visiting the ISS. Initially, four people would stay on the moon for four to seven days, with longer term planning moving to six-month lunar sorties.
The Challenge

The design of new crew transport vehicles will require the incorporation of the best space medicine knowledge and practices, with little latitude and time for the conduct of additional biomedical experiments--on the ground or on the ISS (2). Continued and targeted research into improved countermeasures to space flight deconditioning, therapeutics, surgical procedures, pharmacokinetics, as well as radiation health, benefit future spacecraft design and enhance safety and mission success. To date, significant experience in space medicine has been accumulated. This wealth of information encompasses crew selection, training, and preventive care, spacecraft habitability, extravehicular activities, countermeasures, and physiological responses to reduced gravity exposures, management of medical events, and post-flight rehabilitation and return-to-duty after short and long duration space missions in LEO (3-5). Environmental observations and health hazard assessments are being continuously updated through the habitability monitoring and control of the ISS and the planetary robotic missions.

The space flight environment poses many challenges to human health and survival. Exploration means venturing into new environments. Crews will leave their native habitat, the Earth, and journey into an environment with a host of spacecraft internal and external challenges. Externally, system designers and crews must confront variable gravity, radiation, extreme temperatures, vacuum, and risk of collisions with meteorites and debris, and highly variable atmospheric pressures. System designers must also consider contaminants, such as silica on the Moon and the iron oxides in the dust on Mars, including possible and yet undetected biological hazards. The factors of the external environment create a host of challenges to human physiology, including exposures to prolonged microgravity, extreme non ionizing radiation and excessive gamma rays, x-rays, and alpha radiation (solar events) and galactic high energy particles. In microgravity, sedimentation, buoyancy, and convection are markedly reduced or totally absent. Figure 1 illustrates these phenomena.

![Figure 1: Convection, buoyancy, and sedimentation behavior on Earth and in space](image)

These alterations affect some physiological functions directly, such as fluid redistribution, heat dissipation, respiratory and cardiovascular function, red blood cell production, sensory perceptions, and bone and muscle loss.

Some of the physiological and pathological changes of space flight are presented in Figure 2.
Figure 2: Schematic representation of the adaptation to space flight. Adapted from Nicogossian (6)

The spacecraft atmosphere must contain a consistently proper mixture of oxygen and nitrogen while reliably filtering out impurities and contaminants. The atmosphere must also maintain the correct levels of humidity, pressure, and temperature. In the closed environment of a spacecraft, toxicology and microbiology concerns are also critical. Prevention of the spread of illness among the crew must be taken into consideration during mission design. Crews will require separate work, living, and recreational areas and designers must provide a configuration that is both comfortable and functional. Overall, the configuration of the habitat must be compatible with crew needs and mission objectives.

A space system is designed to successfully achieve mission objectives; this is the system function. The specific parameters of the mission objectives will further dictate the system performance characteristics. Environmental, engineering, and human factor considerations will then guide the system design. A spacecraft designed to travel to and from Mars, for instance, will have highly specific technological characteristics that are likely to be more complex and demanding, and will be different from a craft destined for shorter trips to the Moon.

In order to overcome the environmental challenges, exploration systems architecture will include a life support system that provides all that is necessary to support life: atmosphere, food, and water. Environmental control should contribute to the explorers’ health and well-being by regulating temperature, pressure, humidity, and recycling biomass. Exploration spacecraft should be designed in a way that protects both the component systems and the crew from cosmic and solar radiations. Exploration systems must also provide health maintenance and medical support for the crew. Redundancy in critical systems is a must to protect against the possible failures. Additional resources should be allocated to accommodate critical replacement units for all
missions, where rescue or immediate mission abort and return to the point of origin is not feasible.

Figure 3: Astronaut physician Joseph P. Kerwin performs a medical evaluation on the Commander Pete Conrad aboard the Skylab Orbital Station in 1973

Figure 4: Astronaut-Mission Specialist Ellen Baker, M.D., performs a biomedical evaluation on Cosmonaut Gennady Strekalov while docked during STS 71 – MIR mission in 1995

Physical health and psychological fitness are maintained by additional facilities and communication equipment. Figures 3 and 4 depict the unique considerations to be incorporated into the design of health maintenance and medical care systems in the environments of space. Research into fluids, materials, combustion, and gravitational biology will allow the design process to capitalize on cutting-edge technology.

Design parameters must accommodate realistic system and crew performance attributes. Power and mass place constraints on most aspects of the vehicle design, while attempting to accommodate limitations due to crew size, expertise, and availability. These considerations call for maximum feasible automation. Equipment and operations requiring crew intervention must be relatively user-friendly and easily accessible to all crew members.

Three major bioengineering and technological capabilities will be required to support and safeguard the physical and psychological health of the humans exploring space:

1. Habitability and closed loop life support, including water, food production and preservation, toxicological and microbiological control, and psychosocial well-being. Radiation “climate” forecasting and protection, and maintenance of a healthy atmosphere and gas composition over long periods of time without major reliance on re-supply from Earth.
2. Countermeasures to protect against the high threats and health risks from deleterious effects of space flight, due to the absence of or reduced gravity, penetration by meteorites and space debris, solar flares, and biological contaminations, if any, and/or evolved Earth microorganisms adapting to new environments.

3. Medical training, clinical skills, and medical care capabilities should be commensurate with the health and medical needs requirements of a mission.

The above list is not intended to be all encompassing description of hazards and/or potential threats to be encountered during human exploration missions to the Moon and Mars. However, the three categories constitute the core of the health requirements. Timely incorporation of the health and medical standards into the design of vehicles and mission operations is an essential ingredient to the safety of the human space endeavors.

Resources and Risks

Cost overruns and constrained resources have plagued the development of large human-piloted space projects. These projects often span decades and continue over several administrations and congressional appropriation cycles. With the uncertainty of federal budget allocations, invariably there is a degradation of the system design and performance, greater reliance on ground controllers and crews, and increased acceptance of technological threats and operational risks. On occasion, constrained funding has led to the re-evaluation and under-funding of the high priority biomedical research and human support systems. This acceptance of risks can lead to errors with catastrophic results to life and systems. More often temporary and costly fixes are implemented during the operational phases of space missions, resulting in suboptimal habitability situations and degraded performance of the crew and systems. These risks stem from compromises made during the policy formulation process and decision making based on the best available information. In many instances, risks are either accepted or tolerated with the intent to remediate the situation at a later date when resources or technologies become available. In the mission planning and execution phases of the exploration programs, the decision maker should avoid decisions that require the assumption of accepted and tolerated risks, which may compound among themselves and then result in catastrophic risks.

The Office of NASA’s Chief Health and Medical Officer (OCHMO), is developing space flight health and medical Standards are being developed. The purpose of these standards is to promote the design of countermeasures, interventions, and procedures to ameliorate and/or prevent the deleterious health and performance effects of space flight. NASA’s medical standards generating process will use performance standards to set exposure-type limits and/or fitness for duty standards for dangerous or noxious physical and chemical entities, and for the liabilities of isolation and confinement. Permissible Outcome Limits (POL) that are consistent with physiological and psychological deficits and that are environmentally adaptive, reversible, and without sequelae affecting quality of life, may also be established. POLs delineate an acceptable maximum decrement or change in a physiological or behavioral parameter, as the result of exposure to the space environment, or a quantifiable limit of exposure to a space flight factor over a given length of time (life time radiation exposure). A POL is determined based on the impact the decrement or exposure has on the capability to perform assigned tasks, and its implication for lifetime health status. These standards will summarize the current space medicine
understanding of the exposure and fitness for duty. Deviations from acceptable standards will have to be remediated such that the integrity of the crew is not compromised.

So far NASA medical specialists, working with the aerospace engineering community, have been able to ensure the health and well being of all space crews. No NASA mission has been aborted or life lost due to a medical event. However given the atmosphere of constrained resources, tight schedules, and competing priorities, such a track record cannot be guaranteed in the future.

Based on the historical terrestrial exploration enterprises and precedents (7, 8), experience dictates that a process for rationale allocation of health and medical resources will be required a priori for future human ventures into the Solar System. Technological limitations, finite resources, and bold initiatives will require a re-evaluation of the traditional approaches for biomedical knowledge acquisition. They will also drive a reassessment of the extent and scope of possible and reasonable health and medical services to be provided in the conduct of future human exploration missions, sponsored by the U.S. government.

Any venture into extreme environments, and space in particular, is a risky undertaking (9-15). Explorers must rely on the latest reliable technology in order to reach their destination as quickly as possible, perform the intended tasks, and return home safely. Thus, both government and private-sector chartered enterprises tend to be complex and expensive undertakings. In many instances, as the planning proceeds and expeditions are nearing commencement, resources become more constrained. This results in a tendency toward preserving essential life support systems, while rationing health and medical care capabilities. Emphasis is then applied on further medical screening of participants to identify and remove potential or perceived health risks. Schedules and time constraints in the planning stages of missions can also result in insufficient research into prospective health and medical risk factors. This in turn can lead to inadequate technologies, resources, or logistics available to expeditions into extreme environments. Enabling research for human exploration of space is not a stable and sustained effort and as such is subject to specific mission needs, schedules, budgetary, and political pressures.

A recent study by the National Academies noted that there is a need to develop and provide adequate support to space medicine in the planning phases of exploration missions beyond the Low Earth Orbit (2). Each space mission requires careful risk assessments incorporated into an action plan including the best of health and medical knowledge. An action plan for a productive and safe human space enterprise is complex but must be well thought out and funded adequately in order to develop in a timely fashion specific health and medical capabilities into the design of new space vehicles and habitats (15). Lessons learned by the U.S. Navy leading to the establishment of the Bureau of Medicine and Surgery can be readily adapted to space exploration (14).

In the practice of space medicine, the evidence or experience base is often missing and, in many instances, simply must be extrapolated from other settings. There is often a tendency toward rationing medical care and services, especially given the environmental constraints, lack of supporting technology, ability to mount a rescue mission (not applicable to missions beyond LEO), and the assumed or hoped continued good health status of the crews. Fortunately, given the ability of the human physiology to compensate, such practices rarely lead to major diseases or accidents, but they often result in the poor use of available resources and in the inadequate
provisioning of exploration teams that can be dangerous in the case of unforeseen medical emergencies. Enabling technology and systems developed to support space exploration missions must be robust and able to protect the crews from environmental risks. Medical systems and therapeutics might be used for the first time in space, without prior investigations. Small crew sizes and sparse in space research opportunities will preclude NASA from collecting enough data to fulfill FDA-like study requirements. The link between a drug’s biological effectiveness on earth and in space could be based, with a reasonable assumption, on past experience. Policies regulating therapeutic interventions should allow the medical personnel to make their own best judgments to care for their patients and not inhibit providing the best care possible.

Modern human exploration of the extreme environment is enabled through safe and rapid technological adaptation rather than slow and too often incomplete physiological adaptations. It is generally accepted that safe technology should not present human explorers with additional health and medical risks. Given the above constraints, bioethical considerations should be an integral part of the health and medical care policy formulation process including resource allocation in the formulation of budgets (15, 16).

Methodology and Approach

The GMU research team undertook a literature survey to gather the existing knowledge base on the health and medical care policies and practices for medical support to different mission phases in terrestrial and space settings. Six search engines and five key phrases in conjunction with space exploration, space missions, and space flights were used for this preliminary search. The yield of the search is summarized in Table 1.

<table>
<thead>
<tr>
<th>Source Topic</th>
<th>Google</th>
<th>Uncle Sam</th>
<th>Alta Vista</th>
<th>Science Direct</th>
<th>Medicine</th>
<th>PubMed</th>
</tr>
</thead>
<tbody>
<tr>
<td>In space Illness or Injury</td>
<td>10</td>
<td>3</td>
<td>6</td>
<td>12</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Astronaut Health in Space</td>
<td>20</td>
<td>40</td>
<td>5</td>
<td>10</td>
<td>0</td>
<td>66</td>
</tr>
<tr>
<td>Expedition Medical Care</td>
<td>6</td>
<td>6</td>
<td>8</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>In Space Health Maintenance</td>
<td>22</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Medical Treatments in Space Flight</td>
<td>3</td>
<td>16</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>32</td>
</tr>
</tbody>
</table>

Table 1: Summary of the literature search. Seven sources of internet information and six topics dealing with illness, injury, medical problems, medical treatments and health maintenance of astronauts during space flights were researched.
Only a handful of publications addressing issues relevant to these projects were found. A total of six books and 83 articles in peer-reviewed journals were judged to be applicable to the area of interest. The majority of the publications dealt with the medical systems, protocols, or procedures to deliver care or maintain health of the astronauts. There was significant duplication among the results produced by the various search engines. The best and most reliable results were obtained with the searches associated with PubMed, the National Library of Medicine database. Previous searches also failed to identify information dealing either with health policy formulation for medical support in space missions, or prioritization of risks and resource allocations. The most relevant publication that was found through the search was the NASA description of the research needs for the risks of space exploration, *Bioastronautics Roadmap*, which was recently reviewed and commented upon by the Institute of Medicine (17).

On December 8, 2005, a one-day workshop, Health and Medical Care Policies and Practices in Allocating Resources for Human Space Exploration, was held at the SPP/GMU to address the health and medical resource allocation and priority setting for human space exploration missions. A group of preeminent experts (Attachment I) was invited to partake in this activity. Two discussion papers were provided to the participants, which were developed independently by the NASA experts in space medicine at the Space Life Sciences Directorate, NASA Lyndon B. Johnson Space Center, Houston, Texas, and the GMU research team. In addition, NASA experts presented information on the current resource allocation practices. The workshop participants were asked to comment on the materials and present their views on the subject matter. All of the information and comments were then collected into a final report. A second meeting of the experts was held on January 26, 2006, to review the final document prepared by the research team.

**Discussion**

Stakeholders, the public, and policy makers usually consider the sustenance, health, and safety of the human explorer to be the primary responsibility of the *developer/operator*. To provide for the explorers’ health and medical care, mission planners and managers allocate resources, establish content and priorities, and invest in technology research based on the inputs from the medical experts. Figures 5 and 6 present frequency and ranking of medical events and injuries occurring in short and long duration missions, as reported or observed by the U.S. Astronauts and the Soviet/Russian Cosmonauts. Such data, augmented with the recently published information on the early development of cataracts due to radiation exposures (18 and 19), help with planning for medical support design for future missions. At this time, attempting to classify occurrences of medical events as incident rates as opposed to applying a ranking order might be misleading because of the low number of crew members flown in space.
• **Short Duration (<17 days)**
  - Space Motion Sickness
  - Headaches
  - Upper respiratory tract irritation
  - Facial fullness
  - Sleep disorders
  - Gastro intestinal symptoms
  - Musculoskeletal strains
  - Stress
  - Skin dryness and irritation
  - Minor injuries
  - Urinary retention
  - Mild skin and teguments infections
  - Allergic reaction to dye injections

• **Long duration (>16 days to 14 months)**
  - Headaches and facial fullness
  - Skin abrasions & irritation
  - Nasal Congestion
  - Musculoskeletal strains
  - Minor injuries and bruises
  - Stress and fatigue
  - Gastrointestinal symptoms
  - Sleep disorders
  - Cardiac dysrhythmias
  - First degree burns (on board fires)
  - Systemic Infections
  - Kidney Stones

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**Figure 5: Frequently reported medical events in short and long duration space missions**

1. Space Motion Sickness
2. Headaches, facial fullness and nasal congestion
3. Minor injuries and bruises including skin dryness and irritation
4. Musculoskeletal strains
5. Gastro intestinal symptoms
6. Stress, fatigue and sleep disorders
7. Upper respiratory tract irritation
8. Mild skin and teguments infections
9. Cardiac dysrhythmias
10. Allergic reaction to dye injections
11. First degree burns
12. Systemic Infections
13. Kidney Stones
14. Foreign body in eyes
15. Allergic reaction to dye injections

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**Figure 6: Overall ranking order of medical events reported or observed in all space missions**
All events were comparable to the patient cases handled in an ambulatory setting. Four serious medical episodes, kidney stones, intractable cardiac arrhythmias aggravated with exercise, systemic infections, and severe headaches not responding to conventional therapy, required evacuation back to Earth. Medical events are rare and overall crew health can be protected through careful monitoring and risk management. Figure 7 presents the causes of mortality among the astronauts and cosmonauts. As can be seen from this figure, the in-flight deaths were the result of technology failure and not related to medical events. At this time, all causes of death due to medical conditions occurred long after the space missions were completed, and thus are judged to be unrelated to space flight.

<table>
<thead>
<tr>
<th>Cause of Death expressed as a % of the cosmonaut and astronaut population</th>
<th>Soviet/Russian Cosmonauts (N=91)</th>
<th>US Astronauts (N=295)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Space flight Related Accidents</td>
<td>4.4</td>
<td>3.7</td>
</tr>
<tr>
<td>Training Accidents</td>
<td>1.1</td>
<td>2.4</td>
</tr>
<tr>
<td>Accidents Unrelated to Space flight or Training</td>
<td>1.0</td>
<td>2.7</td>
</tr>
<tr>
<td>Cardiovascular Disease</td>
<td>7.7</td>
<td>1.0</td>
</tr>
<tr>
<td>Cancers</td>
<td>2.2</td>
<td>1.7</td>
</tr>
<tr>
<td>Other/Unknown (no autopsy available)</td>
<td>0</td>
<td>0.3</td>
</tr>
</tbody>
</table>

**Figure 7:** Causes of mortality among Soviet/Russian Cosmonauts and U.S. Astronauts (note data for Cosmonauts is incomplete) expressed as a percent of the total population. N denotes the population size. Each case is assigned one cause of death.

The medical information gathered from in-flight experience can serve as a guide for stratification of standards for NASA spacecraft development projects. On December 20, 2004, the NASA CHMO issued a document containing guidance on *Human Health and Medical Direction for Space Exploration* (Attachment II). This document addressed the health and medical requirements for the development of vehicle design, operations, and research to ensure that the human system is successfully incorporated into all space exploration planning. The intent of the guidance was to maximize preservation of the health of the crew members involved, within mission constraints. This guidance is also consistent with the earlier description of the critical technologies required to maintain crew health and well-being during and after long duration exploration missions.

Currently under the guidance of the OCHMO and using the Occupational Safety and Health Administration (OSHA) as a model, expert groups at Johnson Space Center are drafting *Space Flight Health Standards for Human Performance*. The performance standards will be used to set...
exposure limits and/or fitness for duty for dangerous or noxious physical and chemical exposure in isolated, confined and hostile space environments.

Past research at GMU on extreme environments identified the need for medical policy formulation processes and associated training programs for space explorations. Using the Australian National Antarctic Research Expeditions (ANARE) (15, 16) policies for selection and for performing appendectomies on all physicians wintering in Antarctic as a guideline, an algorithm for medical policy formulation was developed and tested.

The policy formulation algorithm integrates the three elements of space flight architecture: human, system, and environment as presented in Figure 8. The process involves identifying the important problems within the environment, assessing the risks to the human explorers, prioritizing and mitigating the risks, and designing a system around the human explorer that alleviates the perceived risks. Policy formulation must begin by assessing the current knowledge base. Additionally, this must be a continuous process whereby the algorithm must be maximized and changed. For a more detailed explanation, see Part I: Ethical Considerations in Scarce Resource Allocation for Health and Medical Systems Development and Operation (16).

![Figure 8: An algorithm for health and medical policy development process for human space exploration.](image)

Based on the above considerations, the process of risk stratification, policy generation, and resource allocation to research, medical systems development and operations for human space exploration can be implemented. Prioritization of risk is an important element that will influence in the near-term the resource allocation strategy, and in the long term the outcome of the planned expedition. Addressing the threats and risks in relation to the duration of a mission is an important element of the prioritization process in the development of health and medical standards and requirements in establishing the resource envelope. Specifically, the following sources of knowledge should be considered and incorporated into the risk stratification process.
Most of the Earth analogs, by virtue of the presence of gravity, do not have total fidelity of space missions. Bed rest represents one of the means to reduce the gravity gradient created during the upright position; however, bed rest by virtue of the inactivity component is of limited value. Most of the analogs are used to test different life support subsystem components, isolation, remoteness, and confinement. The major usefulness of such studies is to understand psychosocial and compatibility issues, and to gain experience in providing medical care in extreme environments. Analogs to space flight are also useful for evaluating logistics models and verifying the robustness of equipment. Integrating the knowledge from all relevant analogs is beneficial for predicting potential psychosocial problems to be encountered in space flight. Polar and Antarctic (total physical isolation) analogs are arguably the best medical care model as no evacuation is possible. Such notions as justice or priority to the worst off or fair shares cannot be readily adapted or applied to decisions leading to the prioritization of the health and medical needs of space travelers. The principle of maximization of the health and medical care for a given outcome (16), and to some degree equity, can be incorporated into the decision process leading to resource allocation and health policy formulation. Such an approach can improve the chances for mitigation of known health risk(s) encountered in the exploration of space. The risk reduction strategy using the maximization principle should also address the long term explorer’s health and quality of life beyond the successful accomplishment of the mission objectives. An approach addressing resource allocation based on these principles has been proposed by the research team. This Health and Medical Policy Formulation approach is predicated on the stratification of risk leading to policies designed to ensure the efficiency in the use of resources. Continuous evaluations to determine the efficacy, without compromising the safety, of the existing policies and practices should be an integral part of such a process.
Conclusions

Space-faring nations should attempt to mitigate space exploration risks by minimizing or removing known threats, vulnerabilities of the systems (albeit human or vehicular), and their long-term implications to and potential consequences to the health of the space explorers. The space program should evolve along the lines of an occupational health program for timely and proper risk management. Risks that astronauts face during space travel are internal (biomedical or vehicular), external (meteorites or radiation), and systemic (the result of a cascade of events). Risk analysis should be a continuous undertaking since mission planners and stakeholders will be learning more about various obstacles astronauts will be facing in space. Risk analysis must be done by methods that not only include probabilistic analysis, but also worst case scenario and probabilistic tree analysis. Risk analysis relies on databases that are developed from research protocols carried out on Earth using special simulations and analogs duplicating individual or multiple space flight environmental parameters, in space studies, and post space flight follow ups. Critical to this endeavor is the ongoing Longitudinal Study of Astronaut Health (LSAH), (19, 20, and 21).

The LSAH consists of health data, including results from medical selection and annual physical evaluations, collected from astronauts during and after their career as an astronaut. LSAH contains both physiological and medical information. Space flight derived health and medical data has not been fully integrated with the LSAH. It is envisioned that space flight information can be used as an epidemiological tool of the exposure level to the environment of space. Currently there is significant loss to follow up by the LSAH participants who leave active service with NASA. It has been determined that there is a lack of incentive to continued participation, primarily among the individuals who move away from the NASA Lyndon B. Johnson Space Center. One way to increase participation is to provide an astronaut health care for life program for the astronauts and their immediate families, which will ensure standardized care, medical data collection, and generational follow up. Astronaut health care for life should be part of the national legislation process requiring action by the administration and the Congress. Once implemented, LSAH can serve as a model for other space-faring nations to contribute to the codification and standardization of the space medicine program. In addition to the passing of proper legislation, a potential avenue to implement this idea would be to commission the astronaut corps, similar to the Public Health Service and NOAA personnel who put themselves in harms way during the conduct of their official duties. To this end LSAH should continue to receive support and expanded to include health and medical flight data. The research team notes that the LSAH constitutes a unique and major tool for long term health risk assessment to exposures to space flight and should incorporate the space flight data.

In a constrained budgetary environment, healthcare policies act as a guide to bind implementation of a medical strategy, and also to give specific direction for what is an acceptable outcome. Developing and maintaining well documented health and medical standards should be integral part of the NASA space medicine program. The OCHMO is in the process of developing such standards. These standards come in the form of selection and retention standards, fitness for duty standards, levels of care, and acceptable risk expressed as permissible exposure and outcome levels. Each unique mission will have different objectives and different mission architecture. Medical and health risk mitigation must be considered in relation to individual mission’s architecture and objectives. Health and medical considerations must balance
the constraints imposed by the limitations of mass, power, volume, time, and money. Astronauts that require acute care, during a mission beyond LEO, can compromise the mission, mission resources, and the health and lives of other crewmembers. Minimizing exposures to health hazards, either through the use of technology or medical countermeasures, combined with routine health maintenance is more cost effective, hence, a more desirable form of health care delivery. Finally, the estimates of threat, criticality, exposure duration and level, and vulnerability should be an inherent part of any risk assessment.

The National Academies define risk assessment, in an occupational setting, as a four step process consisting of:

1. Hazard identification
2. Dose response estimation
3. Exposure level
4. Risk characterization

Risk management is a “value based” process used to decide which and what degree of risk will be considered significant and ranked accordingly. Thus once a health risk is assessed or understood, its management will include other values encompassing economic, technological, societal, ethical, or legal considerations. Thus perception of the magnitude and acceptance of risks are influenced by factors other than just a set of numerical data. Risks perceived to be voluntary, under one’s control, having clear benefits, fairly distributed and statistical are better accepted than risks considered to be imposed, unfairly distributed or generated by an unreliable source (22).

Proper expression and conveyance of the magnitude of risk is not easy, especially when dealing with health and medical concepts. Lack of adequate space medicine knowledge base, individual’s biological variability and the tendency to fill the knowledge gaps with information from terrestrial settings introduces a certain uncertainty factor into the expression of risk estimates. The GMU research team proposes the use of the following risk assessment approach for consideration by space medicine specialists. The proposed approach is generic by nature and is intended to convey a possible concept for developing a numerical value for risk assessment, management, and communication.

The space explorer’s inherent health risk(s) for developing an illness during his or her lifetime can be expressed as

\[ R_H = S/P \]

Where \( R_H \) is the health risk, \( S \) represents individual’s susceptibility (risk) to develop an illness, and \( P \) can represent the astronaut corps, a control group, or the general population. Careful medical, selection, surveillance, screening, and health maintenance programs implemented for space explorers through their career ensures early detection and intervention to correct health risks. For the purposes of space medicine practice, the inherent or intrinsic health risk can be considered lower than that of the general population.
During space missions astronauts are continuously exposed to multiple environmental hazards (notably radiation, microgravity, habitat toxicology, nonionizing radiation, microbial challenge and many other technology failures threats.) These combined hazards can be expressed as an occupational exposure risk

\[(2) \ R_E = E \times D \times S/P \]

or

\[ R_E = E \times D \times R_H \]

Where \( R_E \) is the risk imposed by the environment, \( E \) represents exposure level, \( D \) represents duration of exposure and \( S/P \) is the susceptibility to develop an illness (see \( R_H \)).

The potential health risk associated with the space systems operations (habitat, space suit, life support, etc.), and amenable to a probabilistic analysis, in turn can be represented by

\[(3) \ R_T = T \times V \times C \]

Where \( R_T \) is the system or technological threat, \( T \) is the threat, \( V \) is vulnerability, and \( C \) is criticality (encompasses consequences and impacts assessments).

The aggregate risk \( R_A \) (combining \( R_H \), \( R_E \), and \( R_T \)) can be expressed using the following relationship:

\[
R_A = \frac{[E \times D \times S/P] + T \times V \times C}{UF} \\
R_A = \frac{R_E + R_T}{UF}
\]

\( UF \) represents the uncertainty factor as related to knowledge and/or clinical experience. The proposed risk assessment approach, which addresses the three elements of an exploration mission, is consistent with prior models and algorithms developed by the GMU research team and encompasses the:

1. Human (\( R_H \));
2. Exploration Systems (\( R_T \)); and
3. Exploration Environment (\( R_E \)).

For each of the subjective or objective elements of the risk a rating scale can be developed and a numerical value assigned. Using the numerical information the overall score for individual risks can then be calculated. This in turn allows risk prioritization and management. For instance, the following classification can be used to qualify the health and medical risk (s):

- **Managed**: a risk which is continuously monitored with the intent to intervene with administrative, financial, or technical actions if the risk exceeds the set limits
- **Acceptable**: a risk which cannot be eliminated, politically and budgetary driven, and subject to either efficiency (Type II reliability) or effectiveness (Type I reliability) (24)
• **Tolerable**: a risk which can be eliminated, but at a significant cost, and is subject to political opinions and decisions
• **ALARA**: as low as reasonably achievable means whatever is technologically or scientifically feasible to reduce the risk at the time of implementation.

This classification can then be used to stratify the severity of risk by providing a qualitative description of the degree of possible damage:

- **None**: no known risks
- **Low**: small probability of life threatening events
- **Medium**: probability of injury or disease which can be life threatening
- **High**: significant probability of death, injury, or disease
- **Catastrophic**: loss of life or significant impairment
- **Unknown**: unquantifiable risk which can range from 0 to ∞

In turn a numerical value can be added to the above qualitative classification of risk:

- **None** (0)
- **Low** (1)
- **Moderate** (2)
- **High** (3)
- **Catastrophic** (4)
- **Unknown** (5)

Full validation and modeling of the above formulas and processes are beyond the scope of this report and should be the subject of additional inquiry to determine relationships and rating scales.

Based on all the information available in the literature and through expert discussions, the GMU team proposed a priority ranking of the health and medical needs for all exploration missions, regardless of destination. In general, maintenance of life support integrity and preventive protocols should be at the core of all missions. Reliance on habitability and environment should be the primary line of prevention since the medical care will always be limited by resources and, especially, personnel. Figure 9 summarizes the proposed priorities for health and medical resource allocation.

### Proposed Priority Setting

- Proper Habitability and Environmental Health
- Preventive Care and Health Maintenance including rehabilitation capability and psychosocial support
- Medical and surgical capacity addressing clearly spelled events (no over promises!)

Figure 9: Proposed priority guidelines for allocation of health and medical resources for space exploration missions
Figure 10: Consequences of medical policy recommendations and management decisions

Management decisions to accept or reject medical recommendations based on risk estimates can enhance or compromise mission success and the health of the explorers. Figure 10 represents possible outcomes associated with such management decisions. When both policy recommendations and decisions converge, the health risks of the expedition are minimized. Disagreements will result in a Type I error, leading to decreased reliability and potential catastrophic outcome, or Type II error, leading to poor efficiency and potentially compromised safety (24). Traditionally, the NASA management has been supportive of the policy recommendations advanced by the medical community.
References


ATTACHMENT I
Health and Medical Care Policies and Practices in Allocating Resources for Human Space Exploration Participant List
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ATTACHMENT II

Human Health and Medical Direction for Space Exploration

On December 20, 2004, the NASA Chief Health and Medical Officer issued a document containing guidance on “Human Health and Medical Direction for Space Exploration.” This document addressed the health and medical requirements for the development of vehicle design, operations, and research to ensure that the human system is successfully incorporated into all space exploration planning. The intent of the guidance was to maximize preservation of the health of the crew members involved, within mission constraints. The following guidance was included in this document:

“……..Environmental health systems designs shall address:

Crew exposure to radiation sources from within and external to the spacecraft regardless of the location of the crew (intra-vehicular activity, extra-vehicular activity, or planetary surfaces).

Crew exposure to toxicological and microbial contamination of internal air, water, and habitat surfaces

Crew exposure to vibration and noise

Human habitability issues should be incorporated in designing space exploration missions and systems. The following human factor design considerations shall be incorporated in spacecraft design and mission operations:

Adequate and ergonomically correct work and living volume

Adequate lighting to assure maximum performance

Adequate areas that allow for restful sleep, and personal physical space

Capacity for exterior views

Environmental controls for temperature, humidity, noise, and odors

Work schedules that are not excessively demanding, and that incorporate sufficient rest and recreation periods

Scheduling that allows for private time

Time and resources for personal hygiene

Nutritionally healthy and palatable varieties of food and beverage, with attention being given to individual crewmember preference and other human factor issues
**Health Maintenance Criteria**

The health status of crew members must be maintained in order to insure their ability to function and perform all assigned duties over the duration of their career as an astronaut. This includes the ability to conduct planned and contingency activities during launch, spaceflight, de-orbit, entry, and landing on Earth or other planetary surfaces, and the ability to execute a contingency egress from spacecraft after all space missions. Crewmembers shall have the ability to maintain health capabilities to allow performance of all required duties during the phases of a mission, including those involving transitions to altered gravitational conditions. Such capabilities include maintaining orthostatic tolerance, sufficient neurosensory function, and physical fitness. Post-mission persistent lasting ill health effects from space flight in low-Earth orbit and exploration missions should be kept as low as reasonably achievable. It is expected that life span and quality of life will not be compromised.

**Crew Medical Evaluation, Monitoring, and Certification**

Crewmembers for exploration missions shall be medically screened, evaluated, and certified using evidence based medical selection and retention.

Clinical evaluation and monitoring of astronaut health shall be conducted at regular intervals to determine medical status during ground based training and space flight. While on space missions, crews will undergo regular, full evaluation of their physical and behavioral health status. Adjustments to their health maintenance program will be made, as necessary, to maintain an acceptable health status during flight, planetary surface deployment, and re-integration to life on Earth. Medical monitoring during unique or potentially hazardous activities, including EVA-and planetary surface exploration, is also required. These evaluations, in conjunction with the physical health evaluations prior to each mission, will establish a baseline normative database against which post-flight recovery will be implemented and evaluated.

In cases where medical intervention is required, medical status will be monitored, outcome recorded, and effectiveness of the intervention assessed.

In order to assist in the medical evaluation and care of space crews, data to establish astronaut population health norms in the terrestrial environment will be collected.

**Level of Medical Intervention and Care Criteria in Space Exploration Operations**

Medical care to maintain the ability to perform assigned duties is required before, during, and after space flight. The level of medical care for a given mission shall be established through a health risk identification, prioritization and management process that balance ethical constraints, knowledge and optimal medical care possibilities against mission and program constraints.
Ultimately the level of medical care should maximize the chances for mission completion and minimize the impact of a crewmember’s illness or injury to any other crewmember. Post-flight health rehabilitation shall also be provided to assist the astronaut for a return to functional baselines in the areas of physical fitness, and physiological and behavioral health. The capability to successfully treat crewmembers for a wide range of illness, injury, or behavioral health problems, and return them to effective duty during the mission shall be developed and maintained.

Medical care capability shall include the following:

Appropriate diagnostic and treatment systems which are commensurate with the level of medical care established for specific mission scenarios; appropriate medical hardware, procedures, and protocols to support cardiopulmonary and trauma life support shall be available within mission constraints.

Crewmember treatment with respect to decompression sickness will be provided at a level comparable to Earth-based standards within mission constraints.

Emergency life support capabilities, cleanup, and decontamination systems will be provided for hazardous (chemical or bacteriologic) exposures. There will be plans for crewmember protection and treatment, and module control, in the event the environment becomes contaminated.

Palliative treatment and comfort measures will be provided for crew members in the event of irremediable injury or the development of fatal disease, within mission constraints.

Medical Management and Training

Provisions for emergency medical services in support of all phases of a mission shall be made available. Adequate medical communications, consistent with the Privacy Act, shall be provided.

Medical and behavioral health training shall be provided for crewmembers consistent with mission demands and limitations (e.g., communication delays). This will consist of each crewmember receiving appropriate baseline medical training and certification, including proficiency training prior to flight, continuing medical education, imaging, telemedicine and training in flight. To facilitate in-flight training and maintenance of skills appropriate portable trainers/simulators to perform routine procedures will be available to crews.

Depending on the size of the crew and mission constraints, human exploration missions shall include a physician who has additional training in space medicine, surgery, internal medicine, otolaryngology, critical care medicine, urology, behavior, psychiatry, gynecology, and gastroenterology. These physicians are specially trained to provide medical care on exploration mission. An important aspect of exploration missions is that crew members may not be in continuous contact with the earth because of delays in communications over such long distances; therefore, the physician must be trained for independent duty without immediate support from
the Flight Surgeons assigned to the mission. Another member of the crew will be given special training in order to assist the physician and provide a level of backup.

**Preventive Medicine and Countermeasures**

A program of preventive medicine, shall be established, and updated, based on research findings, lessons learned, and current standards of medical practice, risk management data, and expert recommendations. This program shall address all mission phases and target human physiologic and behavioral health factors, and required performance capabilities, at risk, as well as interventions, protocols or systems (i.e. countermeasures) to reduce that risk. Pre-flight countermeasures should include crew selection, behavioral health training, physical fitness and exercise, physiological adaptive training, and health stabilization programs. In-flight countermeasures should include those activities necessary to maintain physiological health, mental and behavioral health, nutritional health, physical fitness, and mission performance. Post-flight countermeasures should include those activities necessary to assist the crewmembers in a return to preflight physical, physiological, and behavioral health baselines.

In order to guide and focus this program, medical standards for the development of countermeasures, interventions, and procedures to ameliorate and prevent the deleterious health and performance affects of space flight will be established. Standards will consist of fitness for duty criteria, and other criteria and limits as appropriate. Where appropriate Permissible Exposure Limits that are consistent with physiological and behavioral health changes, which are environmentally adaptive, reversible, and without sequela affecting quality of life and life expectancy will be determined. The following medical standards shall be established:

- **A Permissible Exposure Limit for bone atrophy related to altered gravity**
- **A Permissible Exposure Limit for muscle mass and strength loss**
- **A Permissible Exposure Limit for space flight radiation exposure**

**Fitness for duty criteria for cardiovascular fitness, that will allow crew members to perform all required duties during all phases of a mission,**

**Fitness for duty criteria for neurosensory and motor functioning that will allow crew members to perform all required duties during all phases of a mission**

**Individual and group, behavioral health criteria for crew selection, composition and performance.......”**