National Aeronautics and
Space Administration

NASA

ENGINEERING, LIFE SCIENCES, AND HEALTH/MEDICINE SYNERGY
IN AEROSPACE HUMAN SYSTEMS INTEGRATION

THE ROSETTA STONE PROJECT

Edited by **Richard S. Williams** and **Charles R. Doarn**

Engineering, Life Sciences, and Health/Medicine Synergy in Aerospace Human Systems Integration

The Rosetta Stone Project

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February 10, 2017

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TO: Senior Advisor for Health and Medical Policy

FROM: Chief Engineer
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SUBJECT: Human Systems Integration

Effective human systems integration has perennially posed great challenges across the spectrum of human-rated vehicle design, development, and operations. Examples of suboptimal human system integration are numerous across the maritime, rail, and aviation industries. In human space flight vehicles, effective human system integration is critical due to the constant threat and unforgiving nature of the launch, in-space, and re-entry/recovery environments. In long-duration exploration-class missions, the in-space phase will be even more unforgiving, with little to no chance for recovery or return in the event of system malfunction or failure. Mission success and the lives of the crew will be dependent on reliable systems that are optimal from the earliest phases of design through development.

We would like you to form a cross-discip1ine team to examine differences in culture and practice between the engineering, life sciences, and medical communities. Some of the challenges and failures of human systems integration may be due to problems with communication and cooperation between these communities, each of whom must perform well together for successful design, development, and operations of human-rated spacecraft. Improvement in human systems integration may result from increased cross-cultural understanding and better working relationships between these professional disciplines.

Please submit a report to the NASA Technical Authorities with your observations and any recommendations for HSI improvement by July 2017. We look forward to seeing the progress your team will make with this difficult task.

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Executive Summary

The current "Rosetta Stone" project draws its analogy to the original ancient carved rock decree, engraved in three distinct lexicons to be understood within the context of one another. With this idea in mind, this project was undertaken to examine similarities and differences in culture and practice between engineering, life sciences, and health and medical disciplines in the context of human systems integration (HSI).

The successful design, development, and operation of human-rated systems for space flight requires the combined efforts of engineering, science, and human health disciplines. Each of these disciplines contributes a different set of scientific and technical expertise in addressing the challenges of planning, designing, and operating safely and successfully in the environment of space. HSI can be defined as an interdisciplinary and comprehensive management and technical process that focuses on the integration of human considerations into the system acquisition and development processes to enhance human system design, reduce life-cycle ownership cost, and optimize total system performance. The implementation of HSI is challenging and often fraught with problems. HSI must play an integral and active role in the development of spacecraft and high-performance aircraft. This role must address considerations related to health and safety of the operators and passengers. Complex systems that are not human-rated, operated directly or remotely by humans, must also undergo the HSI process for full success.

The primary goal of the project was to identify and understand differences and to make recommendations for improving the ability of the communities to work together more effectively to improve HSI and systems operations. Notable examples of HSI failures in aviation and space vehicles are provided. The complexities of human-machine interfaces are examined from behavioral health and human factors perspectives. Differences in the ways that engineers, life scientists, and physicians approach problem evaluation and solving are described. Additionally, an innovative approach to human health risk evaluation using sets of ethical principles and responsibilities to guide decision-making in extraordinary risk acceptance is described in detail.

NASA has implemented engineering, safety and mission assurance, and health and medical technical authority as part of its checks-and-balances systems to work with program management. The manuscript describes some of the challenges facing technical authority implementation, especially in the field of health and medicine. NASA life scientists and medical personnel recognized the imperative of effective communication with engineering program management years ago and took steps to improve their ability to communicate with engineering colleagues.

The NASA health and medical system was reconfigured to an occupational health model (risk-based standards to requirements to deliverables) to optimize astronaut health. The NASA Human Research Program (HRP) was integral to these changes, prioritizing its research agenda to address health risk requirements and using system engineering–like tools to communicate with NASA leadership and management. Experts in the HRP have adapted probabilistic risk assessment, a major engineering risk assessment tool, to health and medical risks in human space flight in the form of the Integrated Medical Model (IMM).

The IMM is an innovative tool that expresses medical risk in quantitative terms that are relatable to engineers and interpretable by the engineering community and may also have wide value beyond the realm of human space flight. Human factors experts and other experts in HSI have produced the HSI Practitioners Guide, which provides phase-by-phase guidance for HSI activities and products and has been adopted by NASA's foremost human spacecraft development projects.

This document summarizes the differences in the medical/life sciences and engineering communities of practice, beginning with the substrate on which each community works, continuing through professional lexicon, risk analysis and identification, to risk remediation and problem resolution. Cultural and practical bridges need to be built between the communities of practice responsible for the design, development, and operation of human-occupied and -operated systems. The following are recommendations for improving communication and understanding between engineering and medical/life sciences communities:

1. Recognize the fact that significant cultural differences between communities of practice (i.e., life sciences and medicine) involved in NASA system development and operations exist. These cultural differences pose a risk to effective HSI.
2. Address cultural differences, primarily between engineering and medical/life sciences communities, early in the career paths of practitioners.

Given the importance of human-rated and -operated systems, not just to NASA but also across society, these differences should be formally addressed in the early training curricula of both engineering and medical/life sciences students in their respective professional schools.

3. Develop a common lexicon and common means of communication, methods, and practices that are recognizable and understandable by all, as effective communication is imperative. In NASA, the Technical Authorities and the Mission Directorates should collaborate to produce training modules in NASA's learning management system—System for Administration, Training, and Educational Resources (SATERN)—to promote understanding of cultural differences and improve dynamics and the working relationship between engineering and medical/life sciences communities. NASA should also establish a mandate for the Technical Authorities to emphasize effective HSI and to mediate and translate between the medical/life sciences and engineering communities. Medical/life sciences communities should leverage communication techniques used widely in systems engineering as much as possible. Medical/life sciences communities should utilize engineering risk analysis techniques when feasible. Engineering communities would be well served to formally consider specific, defined ethical principles and responsibilities when evaluating overall risk assessment and acceptance. The field of human factors is critically important as common ground for the intersection of all communities of practice in HSI and can serve as an effective agent and venue for change.

4. Create an imperative that all members of these diverse and relevant communities work together in a common platform to ensure the health and safety of the crewmember and the entire system that supports them from design and construction to operation. The diversity of thought/perspectives from each of the relevant communities is a necessity in order to have successful systems, and as such, those diverse contributions must be actively engaged, encouraged, and respected. Such a paradigm is critical in human space flight as it enters a new phase of deep space and planetary exploration.

5. Recognize that dynamic tension exists between Technical Authorities and program/project management. This tension is healthy in the vast majority of cases and is laudatory for its value in enhancing safety and the overall project/program success. Serious conflicts can arise, however, when differences of opinion between technical authorities and program managers potentially affect budgets and schedules. Firm organizational commitment to fully vetting all opinions, with

senior leadership cognizance of and authority over final decisions, is imperative.

6. Engage the National Academies of Engineering, Science, and Medicine to study and comment on the imperative of cross-community collaboration and communication in HSI. This study could be facilitated by the Committee on Aerospace Medicine and Medicine of Extreme Environments and the Board on Human System Integration.

7. Study the disparate ways in which human factors and HSI are organized and addressed throughout NASA. Disconnects between requirements "ownership" and workforce management from center to center and directorate to directorate might contribute to the HSI challenges currently faced. A multidisciplinary team to fully study organizational challenges to effective HSI should be chartered.

8. Inclusion of all responsible and relevant communities of practice in all phases of the project/program, from design to operations, is absolutely necessary. Inclusion of communities late in the process has demonstrably untoward and sometimes tragic effects.

9. The ethics-based decision-making framework that has been implemented for health and medical risks should also be considered for use in other risk acceptance paradigms. The same ethical principles and responsibilities could be applied to risk analysis, mitigation and acceptance in the safety and engineering realms as well. This would provide a broader context for risk decision-making and result in a stronger foundation to support the acceptance of higher risk levels, particularly in situations where mitigation strategies are inadequate or not available. Incorporation of a formal role for ethical considerations in engineering and safety risk analysis and decision-making could ultimately result in more comprehensive mission planning and management.

10. Finally, stress the importance of organizational leadership in achieving successful HSI. Ultimately, effective HSI is clearly a leadership responsibility. Communication and understanding between diverse communities of practice must be inculcated as an organizational core value, repeatedly emphasized by leadership as an imperative.

The engineering, safety, life sciences, and health and medical communities have an obligation to work together as collaboratively as possible in the processes of HSI. As we move away from Earth in exploration-class missions, this effort becomes even more important. We will not have the ability to abort missions and return to Earth, and repair/remediation of systems failures will be supremely challenging to impossible. The health, well-being,

and survival of our exploration crews depends on successful synergy of the engineering, life sciences, and medical communities of practice at the earliest stages of design.

The chapters in this manuscript have been written by subject matter experts that have years of experience in all three disciplines as they relate to human space flight. The editors and authors sincerely hope that this manuscript proves useful in improving that synergy.

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Applicable NASA Documentation

The following NASA documents apply to this training manual. These are under the authority of the Office of the Chief Health and Medical Officer.

Health and Medical Technical Authority
- NPD 1000.0B—NASA Governance and Strategic Management Handbook
- NPD 1000.3E—The NASA Organization w/Change 17
- NPR 7120.11—NASA Health and Medical Technical Authority (HMTA) Implementation

Medical Quality Assurance
- NPD 1850.1—NASA Medical System Quality Assurance
- NPR 1850.1—Quality Assurance of the NASA Medical Care

Occupational Health
- NPD 1800.2—NASA Occupational Health Program
- NPR 1800.1—NASA Occupational Health Program Procedures
- NPR 1441.1D—NASA Records Retention Schedules
- NPR 3792.1B—Plan for a Drug-Free Workplace
- NPD 1600.3—Personnel Security
- NPR 3600—Attendance and Leave

Research Subject Protection
- NPD 7100.8—Protection of Human Research Subjects
- NPR 7100.1—Protection of Human Research Subjects
- NPD 8910.1—Care and Use of Animals
- NPR 8910.1—Care and Use of Animals (Requirements)

Space Flight and Aviation

- NPD 8900.1G—Medical Operations Responsibilities in Support of Human Space Flight Programs
- NPR 8900.1B—NASA Health and Medical Requirements for Human Space Exploration
- NPD 8900.3—Astronaut Medical and Dental Observation Study and Care Program
- NPD 8900.5—NASA Health and Medical Policy for Human Space Exploration
- NASA-STD-3001 Vol. 1—NASA Space Flight Human System Standard Volume 1: Crew Health
- NASA-STD-3001 Vol. 2—NASA Space Flight Human System Standard Volume 2: Human Factors, Habitability, and Environmental Health
- NASA Aviation Medical Certification Standards

I

The Perennial Challenge of Human Systems Integration: Failures, Compromises, and the Effectiveness of Lessons Learned

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Abstract: The successful design, development, and operation of human-rated and -operated systems requires the combined effort of engineering, science, and human health disciplines. Each of these disciplines produces uniquely trained experts who approach their fields differently from fundamental work to applied practices. Human Systems Integration (HSI) is an important and vital step in the development of human-rated spacecraft and high-performance aircraft. The three disciplines of engineering, life sciences, and health/medicine are critical disciplines that must engage with one another to ensure the health and safety of the operator. They must also include anthropometric involvement of male and female operators who are integrated into these systems or interact with them. This chapter presents some of the failures, compromises, and lessons learned in the complex field of HSI. These lessons illustrate only a few examples of how HSI is required in the design of complex systems and how its success ensures overall crew and mission safety and success.

Keywords: medicine, engineering, complex systems, integration, human factors, HSI, conflict resolution

Introduction

In the realm of aerospace engineering and the physical sciences, we have developed laws of physics based on empirical and research evidence that reliably guide design, research, and development efforts. For instance, an engineer designs a system based on data and experience that can be consistently and repeatedly verified. This reproducibility depends on the consistency and dependability of the materials on which the engineer works and is subject to physics, geometry, and convention. In life sciences and medicine, these apply as well, but individuality introduces a host of variables into the mix, resulting in characteristics and outcomes that can be quite broad within a population of individuals. This individuality ranges from differences at the genetic and cellular level to differences in an individual's personality and abilities due to sex and gender, environment, education, etc.

This human variability presents a daunting challenge to engineers and program managers, who are unfamiliar with, and therefore uncomfortable, addressing the individual or "soft" side of systems development. It used to be thought that "technology + concept of operations = capability". Recognizing the importance of the human in the system, this equation could be modified to this: "(technology + concept of operation) × (human) = capability", where the human in the system becomes a multiplier. Effective human-systems integration (HSI) begins with the acknowledgment that the human is a critical component that must be considered throughout the design and operational life cycle of any complex system. This includes factors such as personnel selection, training, and health/fitness requirements for designated tasks. If a system is designed with HSI as a critical component, then the human in the system is better equipped to operate it safely and minimize impact on health and safety. Conversely, to neglect the human, or short-change HSI in program trade-offs without full awareness of the risk due to requirement deficiencies or lack of expertise, is to put both the humans and the craft in peril, and lifecycle costs for a sustained system may greatly increase.

Challenges and Opportunities

The strength of steel or steel alloys and the flow of fuel into a rocket engine are measured with precision and accuracy. Engineering principles and natural law permit systems to be built that can support the stated objectives—a bridge, spacecraft, a new flight suit, etc. When you introduce humans into this engineering paradigm, everything changes. The "engineered" system

Figure 1.1. Orion capsule. (NASA)

must now incorporate requirements accommodating human variability that will ensure crew health and safety. **Figure 1.1** illustrates the complexity of the interface of the Orion crew capsule. The requirements of any human-rated system must be fully vetted by an inclusive team of subject matter experts, including those individuals dealing with human factors and crew health and safety, at the project onset. The vetting should also include test flights to validate system design.

An engineer will design and build a great system to the requirements that he or she is given, and the system will work. However, there have been numerous examples of human-rated systems where requirements have been incomplete or inappropriate, with problematic or even fatal consequences to the human crew and loss of the vehicle. For example, in the 1990s, in order to drive down costs of procuring new systems, requirements were written in a way that relied on contractors to meet less prescriptive "total system performance requirements." As a result, credible life science or medical expertise inputs to contractors could too easily be dismissed or not even sought. In one particular aircraft acquisition program during this time, recommendations to better support the safety and performance of the aircrew were not incorporated for the sake of schedule, cost, and weight, with some acknowledgment of risk. Years later, related concerns grounded the fleet, impacting the confidence in the system and operations. As a result, some of the

recommendations previously dismissed during development had to be engineered into the system after very public discussions of the issue and at a significantly greater cost.

 A human-centered design approach seeks to integrate the humans into the engineering of the system by accounting for prospective user population physical and cognitive capabilities and limitations. Women in traditionally male-dominated occupations may face sex-specific challenges. Many of these challenges are introduced unintentionally by equipment and/or tasks that are inconsistent with female anthropometry and capabilities. To ensure the health and safety of male and female astronauts during space missions, it is imperative to understand the potential influences of sex and gender on space systems design and operations. "Sex" and "gender" are often used interchangeably, but they are not synonymous terms. "Sex" is defined as the classification of male or female according to an individual's genetics, and "gender" refers to a person's self-representation as male or female based upon social interactions.

Spacecraft and space habitats to support human exploration missions must employ a human-centered design approach to ensure both crew safety and mission success. As identified by NASA's Human Research Program (HRP), incompatible vehicle/habitat design is recognized as a potential risk to human health and performance during space operations. As stated in the HRP's Evidence Report for this risk, "Given that vehicle, habitat, and workspace designs must accommodate variations in human physical characteristics and capabilities, and given that the duration of crew habitation in these space-based environments will be far greater than missions of the past, there is a risk of acute and chronic ergonomic-related disorders, resulting in flight and ground crew errors and inefficiencies, failed mission and program objectives, and an increase in the potential for crew injuries."

Human-system interfaces in vehicles and habitats must consider a crewmember's physical and cognitive performance capabilities and limitations, including effects of micro- and/or partial-gravity conditions; dynamic and sustained accelerations; vibrations; atmospheric makeup, etc.; and other potentially deleterious environmental factors, such as noise, lighting, and visibility. An important factor in the identification of crewmember performance capabilities and limitations is the definition and selection of the appropriate reference crew population.

Ergonomic considerations are a critical element in spacecraft and space habitat design and development to ensure that human performance capabilities and limitations are considered for all vehicle systems requiring crew interaction. Anthropometric criteria for spacecraft and space habitats should

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attempt to maximize accommodation of both male and female populations. It is also imperative for astronaut selection criteria to be consistent with design standards and requirements for spacecraft and critical crew equipment. This has not always been the case. A study conducted in 2002 revealed gaps in accommodating the anthropometric range of members of the U.S. Astronaut Corps for almost every system that crewmembers were required to interface with, either in training or during space flight. Systems, which did not properly accommodate all astronauts eligible for flight assignments, included the launch and entry suit (LES), the extravehicular mobility units (EMU), Space Shuttle seats, Soyuz seats, Russian Orlan suits, and T-38 ejection seats. See **Figure 1.2**. Smaller female crewmembers were particularly affected, resulting in a substantial number of female astronauts ineligible for Space Station expedition assignment. In other cases, this incompatibility was considered a "waiverable" condition, which resulted in the affected crewmembers incurring some undefined, incremental risk of catastrophic injury.

FIGURE 1.2. Astronaut Nancy Currie-Gregg
in the LES aboard the Shuttle. (NASA)

When interpreting anthropometric data, a single measurement or percentile is not representative of a crewmember and should not be used exclusively. Rather, it is important for human factors engineers to work with system designers to identify critical anthropometric dimensions for specific system operations and crew functions. For example, there is a relatively small set of anthropometric dimensions considered critical for EMU design, such as chest breadth and biceps circumference. Population analysis can then be used to determine the range of accommodation, usability, and operability within the context of the targeted user population.

The following is an example of how subsequent changes to a vehicle design can lead to human-systems integration issues, particularly with respect to anthropometric differences between males and females. Following the Space Shuttle Challenger accident, a new method for crew escape was implemented for scenarios in which the Orbiter was in controlled flight but unable to successfully reach a runway. This escape system, manually activated by a flight crewmember in the middeck of the Orbiter's crew compartment, relied on deployment of, and attachment to, an escape pole, which helped guide crewmembers clear of the orbiter's wing. Implementation of the escape system enacted requirements for crewmembers to wear a pressure suit during launch and entry. The suit selected was similar to those worn by high-altitude pilots in the U.S. military and built to anthropometric specifications to accommodate the American male military aviator population. Female anthropometric measurements are typically smaller than male measurements; however, the major exception to this generalization is hip breadth—average female hip breadth exceeds that of males. Shortly after the use of pressure suits was introduced, it became apparent that suit cooling to maintain the crew's core body temperature within prescribed limits was necessary. After failed attempts to achieve the desired level of cooling using forced air, a liquid cooling garment was fielded. By the mid-1990s, the LES ensemble included not only the pressure suit but also a thick diaper, a G-suit, and a liquid cooling garment. All these additional accoutrements increased the hip breadth by approximately eight inches and served to further exacerbate a pre-existing issue with females attempting to fit into a suit designed to accommodate the hip breadth of the male population. Ultimately, many female astronauts were outfitted with a larger size pressure suit, simply to accommodate their hip breadth. In the event of failure scenarios, which caused the suit to pressurize, this could lead to issues with visibility and manual dexterity, which potentially could, in turn, affect crew performance.

The National Academy of Sciences' decadal survey in 2011 emphasized the need to examine and understand the influences that sex and gender have

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on physiological, psychological, or behavioral changes that occur during space flight. In response, NASA has focused on identifying cardiovascular, immunological, sensorimotor, musculoskeletal, reproductive and behavioral implications on space flight adaptation for both men and women. However, continued research concerning sex-specific physiological differences, including differences in responses to prolonged exposure to microgravity, is vital to enhance understanding of how these differences may affect mission success and/or crew health and safety.

One noted difference affecting female astronauts is that women may be at a higher risk for radiation damage than men, which could ultimately result in more restrictions for long-duration mission participation. Thus, radiation shielding technologies and techniques should be explored in order to equally accommodate both sexes. Female astronauts may also be more susceptible to orthostatic intolerance, which may affect their ability to self-egress following spacecraft landings if mitigations, such as properly fitting G-suits, are not provided. Women also tend to experience more adverse drug reactions than do males, and insufficient research and knowledge of safe dosing for women has led to accidental overmedication. Another safety concern is radio communication between the sexes, because men's ability to hear high pitches degrades with age, and female voices tend to be higher pitched, leading to potential communication issues between crewmembers or between the crew and ground controllers.

Within the past few years occupant protection standards have been developed and incorporated into Human-System Integration Requirements (HSIR) for both NASA and Commercial Crew Program spacecraft. Injury risk functions based on anthropomorphic test device (ATD) responses and Injury Assessment Risk Values (IARVs) have been developed for both 5th-percentile females and 95th-percentile males. However, additional research is needed to determine differences between male and female physiological responses to dynamic accelerations, such as those incurred during spacecraft capsule landings, which can result in crew injury. One reason for this knowledge gap is that the majority of the datasets used to determine biodynamic limits for injury prevention, such as those from the U.S. military, are primarily based on male subjects. Recently, research on sex differences with respect to biodynamic responses to dynamic accelerations has been conducted by the automotive and military sectors. However, this sex-specific research has not been transformed into appropriate sex-specific injury risk limits for human space flight, and further study is needed.

The following section provides several specific examples of inadequate or faulty HSI that led to compromise or system failures.

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Examples

SpaceShipTwo

On October 31, 2014, Virgin Galactic's SpaceShipTwo, piloted by Peter Siebold and Michael Alsbury and under development by Scaled Composites, crashed in the Mojave Desert, resulting in the death of copilot Alsbury and significant injuries to pilot Siebold (**Figure 1.3**). The National Transportation Safety Board (NTSB) ruled this as pilot error in premature unlocking of the spacecraft's reentry feathering. Scaled Composites, in its hazard analysis, failed to account for the possibility of premature unlocking of the feather due to human error in its cockpit design phase. The flight test data card indicated the copilot was to unlock the feathering system at an air speed of Mach 1.4 during the boost phase of the flight. The feather was unlocked prematurely at 0.8 Mach, which led to the breakup of the spacecraft.

NTSB found that Scaled Composites did not emphasize human error in the overall execution of its SpaceShipTwo program. The lack of oversight and guidance in the emerging commercial space flight industry was probably contributory to the mishap. The specific outcome of this tragic event was the design and integration of a device that inhibits premature feather unlocking.

FIGURE 1.3. SpaceShipTwo. (Jeff Foust under CC BY 2.0)

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Space Shuttle Launch and Entry Suit

In the early Space Shuttle Program, there was no way for the crew to escape from the orbiter unless it was on the pad or had landed safely. During the flight phases (launch and landing), crew escape was not available as the systems were not designed for this potential scenario. After the Challenger disaster, modifications were made to the orbiter and to crew training that would permit egress at a certain timeframe during the descent phase. In addition, the LES worn by Shuttle crewmembers was also redesigned. The first LES system used an air-cooled garment, which was not efficient in removal of the metabolic heat load, which led to an increase in orthostatic intolerance affecting almost one third of the crew. The new LES included a liquid-cooled garment that corrected the problem.

This major redesign of the LES was also required to accommodate crew walking. Short bouts of exercise resulted in an accumulation of CO_2 in the suit, which hindered crew performance.

Apollo 13 Carbon Dioxide Removal from the Spacecraft

In preparation of the Apollo 13 spacecraft for launch, a problem was discovered in an oxygen tank in the service module. Engineers at both the Kennedy Space Center and the Manned Spacecraft Center (Johnson Space Center) conducted testing and evaluation and determined it did not need to be replaced. After nearly two days in transit, the crew began to prepare the spacecraft for lunar rendezvous and orbit. Shortly after a series of procedures, an explosion occurred. This explosion changed the course of the mission and greatly impacted the safety of crew. While they could not simply turn around and return, they had to continue around the moon and begin their return.

The explosion crippled several systems on the Odyssey, including CO_2 removal. Engineers and physicians worked with the crew to design makeshift systems to reduce CO_2 by using equipment onboard. This included using Aquarius, the Lunar Module for power and temporary crew quarters until the descent phase and splashdown.

International Spacecraft Docking

In the early 1970s, the U.S. and the Soviet Union agreed to a docking mission of an Apollo capsule and a Soyuz capsule. The two spacecraft had different atmospheres, so engineers and physician with different skill sets, language, and culture developed and tested protocols for docking and conducting joint on orbit operation. The concern of all was the need for crew health and safety and prevention of decompression and the bends.

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This early work demonstrated the need to work closely together and served as the foundation for the current multinational effort in the International Space Station Project.

U.S. Navy's Littoral Combat Ship

The U.S. Navy's new Littoral Combat Ship (LCS; **Figure 1.4**) is designed to be more automated than most of the Navy's ships, which means less human interface. It also was designed to operate close to the shore. Setbacks in design and performance have resulted in delays and cost overruns. Recent failures point to the lack of HSI in the planning and operations of the ship. According to a Government Accounting Office (GAO), the original design of the ship was to include a crew of 55–60, but workload studies have found the LCS to be understaffed based on the original design. The GAO reports that 12 ships were built before the design was fully tested. This includes all the tasks associated with maintaining the seaframe and getting it ready for the next mission operationally. The GAO reports that sailors aboard the ships are averaging just 6 hours of sleep, due to the amount of work that needs to be done in maintaining the system and training. This report also indicates a lack of understanding on how the systems could be maintained without the added cost and additional support from contractors.

FIGURE 1.4. USS Freedom (LCS-1). (U.S. Navy/JoAnna Delfin)

While some tasks could be accomplished with a certain crew comple-
ment, some cannot. This requires redesign in training and increased person-
nel as well as system components.

Conclusion

Engineers, life scientists, and physicians all approach the same developmen-
tal problem differently. While the scientific method is part of the training
for each discipline, the approach to solving problems is performed in unique
ways. While there are many reasons for these differences, the ability for each
of these diverse disciplines to communicate effectively with each other can
enable better design and potentially avoid serious or fatal consequences that
only become apparent in the system operations phase.

The practice of medicine is subjective. Think of the subjective, objective,
assessment, and plan (SOAP) notes that a physician uses. An engineer will
use standard tests with expected outcomes based on empirical and research
evidence. A physician will conduct a variety of tests and may have to try
multiple interventions that may or may not answer the questions or lead to
resolution of the problems at hand, due largely to the variability and ever
adapting and changing nature of biologic systems.

An organization that has the responsibility to build a spacecraft, put a
human in it, and send it into space must bring multiple disciplines together to
achieve this goal. HSI is an integral component of all three disciplines. The
human factors communities of practice, from human factors engineering to
behavioral health practitioners and researchers, are critical to this endeavor.
HSI is concerned with the integration of humans into all systems, specifically
where the human is operating, maintaining, and supporting the assembled
system. When the engineers are given the task to build a system that involves
humans, the risk of catastrophic failure increases if the "human" elements are
not fully and adequately addressed. Therefore, it is absolutely imperative for
every discipline to be present and to actively participate in the early design
phase, and each subsequent design and development phase, until the system
is fully operational.

The profound differences between the fields of engineering, life sci-
ences, and medicine will be explored in this manuscript. Possible reasons
for the differences in practices in these communities will be discussed, and
examples of effective communication that are enhancing systems develop-
ment and HSI will be provided. The adverse impact of other dynamics, such
as cost and schedule, will also be explored. It is the hope of the authors

that this manuscript will enhance understanding and cross-cultural/scientific communication between the disciplines of engineering, life sciences, and medicine, resulting in improved HSI for all human-rated systems, especially exploration-class space vehicles. If HSI is ineffective in exploration-class space vehicles, the mission outcome will likely be catastrophic failure with loss of crew, based on flight duration and inability to abort with timely return to the planet. We cannot afford to make the kinds of errors in HSI that have been made in legacy systems—we must get this right before the mission launches.

2

Technical Authority in NASA

Mark Weyland, MS

Abstract: NASA Technical Authority (TA) is a part of the governance model the Agency utilizes as part of the checks and balances to ensure that decisions have the benefit of different points of view and are not made in isolation. TA is kept separate from programmatic authority to provide independent oversight of programs and projects without cost and schedule pressures. TA originates with the NASA Administrator and is formally delegated down to specific individuals who have authority for one of the three TA disciplines: (1) Engineering, (2) Safety and Mission Assurance, and (3) Health and Medical. Communication is more challenging for the Health and Medical Technical Authority (HMTA) for two primary reasons. First, there are not sufficient HMTA representatives spread throughout the programs and projects as baseline support. This was actually done with forethought, but the workaround, discussed below, isn't working. Second, the nuances of medical risk can be very different from engineering risk, and most design engineers and program/project managers have backgrounds in engineering and not the health and medical disciplines.

Keywords: technical authority, engineering, health and medical, governance

Introduction

Following the Space Shuttle Columbia accident and a subsequent Columbia Accident Investigation Board (CAIB) recommendation, NASA established independent technical authorities as part of a set of checks and balances for programs and projects. It was felt that cost and schedule pressures, inherent in any program or project, contributed to some hazards being minimized, ignored, or not brought forward to higher levels of management, ultimately leading to mission failure and loss of life. The cost and schedule pressure issue was removed by establishing independent technical authorities, organizationally separate and funded outside of programs and projects. They were given responsibility for ensuring standards and requirements were implemented correctly as well as dispositioning variances to those requirements with a direct path to the NASA Administrator if necessary.

NASA established independent technical authority (TA) oversight for (1) Engineering (ETA), (2) Safety and Mission Assurance (S&MATA), and (3) Health and Medical (HMTA). These three areas were selected to encompass a majority of technical standards and to ensure that decisions have the benefit of different points of view and are not made in isolation. NASA separates the roles for programmatic and technical authorities to provide an organizational structure that emphasizes the Authorities' shared goal of mission success while taking advantage of the different perspectives each brings. Technical authority originates with the Administrator and is formally delegated to the NASA Chief Engineer for ETA; the Chief, Safety and Mission Assurance for S&MATA; and the Chief Health and Medical Officer for HMTA. Subsequent delegations are made to selected individuals at center organizational levels.

Challenges and Opportunities

Some of the possible reasons that health, medical, and performance requirements not adequately addressed in the early phases of vehicle design are inadequate communication, poorly written and understood health and medical standards, and the fact that NASA is predominantly an engineering organization. The engineers in charge of designing and operating human-occupied spacecraft simply are not trained in the specific disciplines encapsulated by health, medical, and human performance. Many times in NASA's history, these requirements have been an afterthought, which has resulted in either higher cost, higher risk, or both. Having an independent HMTA, in theory,

forces programs and projects to address these issues earlier in the design life cycle. Unfortunately, in practice, the HMTA is not funded appropriately, resulting in too few health and medical personnel to adequately address the issues raised. Further, the delegated TA personnel who would help the programs and projects catch issues early on simply are not fully integrated. The Agency recognized this resource gap when the three TAs were established and has attempted to use ETA and S&MATA personnel as the eyes and ears to catch health and medical issues on their behalf. This has limited effectiveness. ETA and S&MATA personnel cannot be adequately trained, and their educational background and work experiences (mostly engineering) do not lend themselves to understanding the different nuances in medical risk arising from the many disciplines with human health and performance as an endpoint. As a result, many health, medical, and performance requirements are either misunderstood or missed entirely until the issue reaches a higher level where trained personnel intervene. This "late" intervention usually increases cost, risk, or both.

Opportunity exists however, to not only provide better service to programs and projects by identifying and helping solve issues and meet health, medical, and performance requirements, but to also educate the broader engineering community. This opportunity exists by adequately funding and staffing the HMTA with enough properly trained personnel who would "live" within the programs and projects (the same as ETA and S&MATA personnel) and be part of the team from the beginning. While independently funded, these TA personnel would be seen as assets and not as burdens throwing requirements over the fence without follow-up or support.

Conclusion

After the Columbia accident, NASA established TAs to play an influential and relevant role in providing alternate perspectives in the program and project decision-making process and alerting the Agency to potentially hazardous conditions. TA responsibility for establishing requirements as well as waivers to those requirements calls for in-depth knowledge of the program or project and frequent, effective communication with the project managers and higher level Agency officials. All TAs share the challenge of ensuring that enough of the right people—those with proper training and education—are embedded in the right places of the program or project. The HMTA has the additional burden of educating, explaining, and justifying decisions on requirements that are not as familiar to the design engineers and program/project managers

due to the very different nature of requirements with human health and performance as an endpoint. Former NASA Administrator Charlie Bolden said, "Technical authority is an important voice at the table. It is integral to how we do our work and it is part of a team environment ensuring that we invite, listen to, and value all viewpoints."

3

The Complexities, Risks, and Rewards of Human/Machine Interdependent Space Systems and Missions

Marc Shepanek, PhD, and Cynthia Null, PhD

Abstract: The complexities, risks, and rewards of human-machine interdependent space systems and missions are human endeavors, whose ultimate mission is to enable human understanding and meet human goals. The chapter addresses principles and requirements of design to engage the strengths of machines in computation, precise action, and repetition and human strengths in flexibility to resolve unanticipated dynamics and maintain goal orientation through unforeseen circumstances. Cognitive processes that act economically and efficiently, demanding few resources, and cognitive processes that are intentional, making choices and decisions consciously on what to think and do, are highlighted. The pivotal concept of human error and demonstrated effective approaches are included in the analysis, as is a focus on the strengths of diversity in effective human machine functioning. The development and application of these cognitive processes is the focus of this chapter.

Keywords: human-machine interface, human-machine interdependence, human-machine strengths, human-machine challenges, human-machine error, human-machine diversity, human error, machine error, cognitive diversity

Introduction

A wide range of machines have successfully traversed space from Sputnik to Voyager, Venera to Mariner, Rosetta to Opportunity, not to mention the great observatories: the Hubble Space Telescope, Compton Gamma Ray Observatory, Chandra X-ray Observatory, and Spitzer Space Telescope. Each of these complex systems was engineered for and has endured high acceleration, extreme heat and cold, intense radiation, high impact, clouds of superheated sulfuric acid, rust-laden dust storms, and complete vacuum. All of these spacecraft achieved milestones in science and exploration despite mistakes made in grinding the lens for a mirror, not accounting for environmental factors on a planetary surface, and even the direct impact of radiation. The history of crewed space missions is replete with triumph and tragedy: Yuri Gagarin on Vostok 1, Neil Armstrong on Apollo 11, Soyuz 11, and the loss of Challenger and Columbia.

These missions are human endeavors. They were, and future missions will be, conceived to meet human goals to explore and understand our world, our galaxy, and the universe. From conceptualization, to design, to hardware development, to launch, to mission control, to data gathering, to transmission, and to spacecraft return, missions are created and managed by humans. Safety and success have always been and will always be dependent on engaging the strengths and addressing the weaknesses of humans and machines.

Early spacecraft, such as Gemini and Apollo, were developed at a time when the field of human factors was still in its adolescence. Nevertheless, human factors' design principles were applied to controls and displays, as well as to seats and suits to protect the astronauts and enable them to perform their tasks. From a human system integration (HSI) approach, there are at least three principles that must be applied to all human-tended missions, as well as to mission systems and artifacts design: (1) mission demands on the humans are compatible with human capabilities and limitations, (2) mission systems take advantage of unique human capabilities enabling use of human capabilities in non-routine and unpredicted situations, and (3) systems can tolerate and recover from errors (both machine and human). By human capability, we are referring not just to physical capability and health status, but also to all the human activities that result in mission success, including perception, cognition, and analysis and problem solving. To enable such design, we need to understand ourselves as well as our vehicles and other critical mission systems in context. The result of considering the respective strengths of machines and humans in environmental context will be more appropriate task assignment and system complexity. Machines used for computation,

repetition, and precise action in conjunction with humans anticipating problems, engaging flexibly to resolve unexpected dynamics, and maintaining orientation and progress will serve to accomplish mission success.

Evidence

Based on decades of research by behavioral and cognitive sciences as well as neuroscience, two types of cognitive processes have been identified to account for human behavior broadly described as automatic and controlled, Systems 1 and 2, respectively. System 1 processes act economically and efficiently and demand fewer resources, automatically handling much of our daily activities. System 2 is how we think of ourselves—that is, the conscious, intentional, reasoning self that has beliefs, makes choices, and decides what to think and do. We believe we know what goes on in the mind. How we perceive ourselves thinking is a very limited view. Our capabilities are much richer.

There is just too much information in the world. Our systems are sensing and processing massive of amounts of information continuously. A poorly designed system will be swamped with the sheer volume of information. Without the ability to act fast in the face of uncertainty, we as a species surely would have perished long ago. Although incorrect behaviors may attract our attention, analysis of human capability should have us marveling at its preponderance of correct actions, new ideas, creative solutions, and resilience.

Both systems learn throughout our entire lives. Some functions of System 1 are shared across individuals, and others are quite specific to specialized experts. System 1 analyzes the world, protects us, learns from both correct and incorrect responses, and makes suggestions to the slower, more deliberative System 2. This is an important distinction. Designing based only on insight into System 2 capabilities and processes is insufficient and increases mission risk. To meet our design principles, the design takes advantage of both systems. Because System 1 is silent, the understanding of the role a human capability plays in mission success and how to design to meet these needs requires domain knowledge and scientific methods from behavioral science and human factors.

Humans are flexible, creative, and adaptable. We have a vast set of skills acquired over a lifetime of trial and error. We successfully live and adjust to the ever-changing, complex natural and social environments. We successfully work and adapt to complex engineered environments and technologies. Human performance needs to be understood in these contexts, with the understanding that new environments and new missions may require

novel approaches to support human performance. The ability of System 1 to recognize patterns and generalize solutions to new problems is key to successfully coping with non-routine and unpredictable situations. Understanding expertise is not a matter of examining what an expert knows by asking System 2. Training expertise is not just a matter of training System 2. That is, training content and methods must reflect not just the hardware design and tasks, but they must also support development and retention of knowledge and expertise.

To control the human-machine interface, is it possible to protect the system with more rules, tell people to put in more effort, be more careful, and otherwise actively enforce compliance? General research in this area suggests that this is not an effective approach. Telling people what they should have done in the past and ignoring the active processes of humans in an environment is not likely to be productive. Issuing orders to humans to engage with repetitive, machine-like precision while reducing autonomy, variety, diversity, creativity, and reactivity is asking humans to engage machine strengths while stripping them of human strengths. This process effectively makes those systems less flexible and less adaptive and plays less to the respective strengths of humans and machines. Instead of trying to protect systems from their human and machine components, a better approach would be to engage the respective strengths of machines and operators.

It is natural that many of our concerns about space safety and human performance focus on the potential for human error since there may be little recourse for correction in complex, high-risk space operations where degraded human performance may have disastrous consequences. The descriptions of how humans succeed, and sometimes fail, often differ only by the outcome. The expression of expertise and error are governed by the same processes. Our scientific understanding of human error does not come from studying error as a separate process, but rather, by understanding human behavior.

It is not erratic behavior, accident-proneness, or even personality factors that are useful in predicting accidents, despite conventional wisdom that errors are the result of human predispositions to unreasonable error or risk taking. Analysis in hindsight frequently creates a seemingly straightforward path to the individuals to blame. However, this approach does not consider environment or interaction. A pivotal concept for human analysis is that the label "human error" is an attribution, not a fact. Attribution theory has demonstrated that outside observers often postulate personal characteristics as the cause of behavior that has a negative outcome, not the context or environment in which the behavior took place. Conversely, research has shown that when individuals are asked about negative outcome resulting from their

own behavior, they attributed it to environmental, not personal, factors. So, a video recording of a car running a red light would commonly be judged by a third party as being the result of an irresponsible or inattentive driver, though the driver would likely attribute the behavior to environmental factors or a competing goal (such as emergency assistance). The fundamental attribution error emphasizes personal characteristics and minimizes situational explanations when judging the behavior of others, and it conversely emphasizes the situational explanations and minimizes personal characteristics when judging one's own action.

Working backward from an outcome can result in an analysis that oversimplifies a chain of events, creates a false impression of the obviousness of cause, and imputes knowledge to the actors that they did not and could not have had, often ignoring or misunderstanding the positive contributions of System 1. This can result in conclusions in which uncertainty is underestimated and in suggested solutions that may be too simple, mechanistic, and focused on the past. After a mishap, such as an off-nominal landing of an aircraft, one might conclude that the pilot failed to monitor airspeed based on the observation that the landing speed was greater than necessary. The pilot may not be able to provide a satisfactory explanation as to why they landed at that speed. Although pilots are using procedures and actively engaging System 2, System 1 is analyzing sensory data such as visual, auditory, olfactory, or vestibular, comparing with patterns, and using expertise to guide actions. Airplane response to specific mechanical as well as environmental factors, known by System 1, may be influencing the choice to land with a speed exceeding known minimums to provide a safety margin.

NASA is an engineering organization engaging in challenging scientific missions on the world stage. Engineering education is highly specialized. Trained to solve problems, engineers strive to define and work with mathematically precise requirements. From students to seasoned professionals, NASA engineers work not only as individuals, but also in teams, to solve problems and create technology to safely perform specific tasks. Training in engineering includes the mastery of specialized vocabulary, experiential learning, integration of specific values, and a hierarchy of conceptualization and development for work products. In short, engineering education initiates and inculcates engineers and engineering culture to solve engineering tasks. The human adds the educational and cultural set of being an engineer to their identity. Basic engineering education does not require substantial training in human factors; it requires training in addressing defined requirements. Human engineers build spacecraft. It is incumbent on any one or institution that wants to affect this process to understand it and work within

its structure. From astronaut to scientist, physician to politician, remaining stovepiped within our own culture, language, and informational rhythm is an ineffective way to achieve anything.

Diversity is a strength in formulating ideas, conceptualizing approaches, considering alternatives, and solving problems. A range of training in different scientific or engineering disciplines, cultural background, upbringing, thought processes, and life experiences is an asset. Communication, on the other hand, requires precision. Especially for space mission development, it is important to understand the life cycle of an effort, have a common understanding of terms, know where inputs are required or can be accommodated, and know what outputs are needed.

NASA's ability to integrate the best of human thought, ingenuity, and hard work will be defined in large part by our success in bridging the gap between human and hardware—the human-machine interface. There is a broad spectrum for the human factor, from physiology to human factors engineering. Engaging the full spectrum increases the odds of success, and ignoring any portion courts disaster. At NASA, human factors is a critical discipline for assuring that the Agency's work efforts and projects are formulated and designed in such a way that the people performing operations—whether they are astronauts, pilots, launch and mission controllers, or thousands of others with direct contact with mission systems during manufacture, testing, integration, and maintenance—can perform their functions effectively in the environments where the functions must be conducted. NASA human factors professionals conduct research on human performance, develop requirements and guidelines for designers, and engage in operations support at every level. Human factors subject matter experts are occasionally a resource in identification of mishap root causes and hazards. Human factors can include psychiatrists, psychologists and other behavioral health professionals. NASA has ten field centers; all have behavioral health support staff, five have identifiable human factors organizations and personnel, and over half engage in or support research involving some aspect of human factors.

A productive approach to mission development is to acknowledge the complexity and uncertainty of the unknown and actively engage more human strengths. Mission success could be increased at the human-machine interface by engaging well-designed and -maintained machines to provide useful information and action in a reliable manner. Nevertheless, mission success may be better served by increasing, not decreasing, access to human foresight, insight, planning flexibility, analysis, and creativity at the human-machine interface.

By developing an understanding of the critical process of engineering, human health, and human factors, it will be possible to integrate the strength of machines with the flexibility of humans. In short, a well-designed human-machine interface. Without that advance effort and integration, design flaws will propagate. Moreover, in a worst-case scenario, space missions will be forced to rely on the strength of humans and the flexibility of machines. We can choose a better path.

4

Differences in Physician, Engineer, and Life Scientist Training, Practice, Problem Solving, and Approach to Failure

Daniel Buckland, MD, PhD, MS, and Sarah Miller, PhD

Abstract: Many of the failures in communication among physicians, engineers, and life scientists may be due to the differing ways that they approach problems. More than mere personality differences, physicians, engineers, and life scientists are trained with different problem-solving philosophies and strategies. This chapter discusses these differences, provides several example problems that characterize these three different ways of thinking, outlines the corresponding differing approaches to failure, and concludes with a glossary of some terms that are used in different ways across these three fields.

Keywords: physicians, engineers, life scientists, problem solving, failure analysis, communication

Introduction

Inherent in the complex problem solving required in human exploration of space are interactions between physicians, engineers, and life scientists. Conventional wisdom suggests that when one corrals several intelligent individuals in a room, progress is made. However, as the information and theoretical examples below demonstrate, when differently trained individuals come together to solve a problem, each has different assumptions about the problem-solving framework that will be employed—and, typically, an individual does not realize that these different frameworks exist. Greater understanding of the framework and context of each profession may reduce interdisciplinary misunderstandings, allow complementation of each profession's strengths and weaknesses, and ultimately lead to more efficient collaborations, while a combination of these three different approaches may yield more robust solutions.

The three types of problem solvers presented below—physicians, engineers, and life scientists—are meant as archetypes. Of course, individuals would use a mix of these problem-solving methods based on their knowledge and experience, but they may never have received formal training in methods other than the ones specific to their field of expertise. These simplistic descriptions are not meant to imply that all individuals in each of the described groups are alike or that they are incapable of utilizing multiple problem-solving frameworks. These archetypes were developed based on the experiences of the coauthors, who have an MD, a PhD in Aeronautics and Astronautics, and a PhD in Biochemistry between them with relevant academic, government, and industry exposure.

The Three Types and Their Approach to Problem Solving

The Physician

Physicians are trained in medical school to think about differentials and categories. A patient's presenting signs and symptoms are processed, then historical information is used to determine the most common diagnosis associated with that dataset, with highly dangerous but less common diagnoses also included. More complicated tests are applied based on both the common and dangerous potential diagnoses, and then treatment is often based on the outcomes of those tests. This is a categorical approach to problem solving; the physician tries to determine what category the patient belongs in, and then treatment is based on the assigned category. This is a very efficient

system when a patient has a problem that has been encountered before and when there exists a dataset to which the patient can be matched. Often, a thorough dissection of the problem is not even needed because this problem-solving approach is based on probabilities. Computer programmers would refer to the physician's approach as searching a "known set," which is often the fastest way to find a solution if the solution is in the set. However, when the patient has a novel problem, this is a very inefficient approach, as the physician moves to less and less common solutions; that is, the known set approach is the slowest if the solution is not in the set, as all possibilities must be excluded before determining that the answer is not there.

The Engineer

If the physician is trained to solve a problem by applying a known set of solutions that can be applied, then the engineer is trained to take a known solution and then use that as a starting point to formulate a more specific solution that applies to the discrete problem at hand. Both can be compared to the life scientist starting with a new set of hypotheses for each problem. Like the life scientist, the engineer tries to break down the problem; however, the engineer does not break it down all the way if this level of detail is not required to solve the problem. Thus, the engineer is not always looking for root cause when creating a system or novel solution. Instead, the problem is only simplified to the degree required to yield a solution that works with the least amount of change from the current paradigm (however, see below for further discussion of how engineers determine root cause in failure analysis). Going back to our programming analogy, this is a "local search," in that the engineer is looking for an efficient way to find an optimal solution. The search is completed as soon as more solutions do not improve on an already established solution, but it may miss a more optimal solution that is not close to initial parameters of the search.

The Life Scientist

In contrast to the physician and engineer, who each have the goal of producing specific desired outcomes, the goal of the life scientist is to thoroughly understand a biological process or system that already exists. The life scientist is trained to explore biological problems using testable hypotheses and, critically, control experiments to isolate all the key components of a biological process and determine how they work together to facilitate that process—in other words, application of the scientific method to understand how living systems work. Addressing problems in this way is more resource- and time-intensive than the physician's method, but if the proper hypotheses

are posed, this system can handle a broader range of problems and generate new data that are applicable to other problems. Programmers would call this approach a "global search," which is often the least efficient way to find a solution, but the solution found would have a higher chance of being the optimal solution because (ideally) it considers the most information.

Three Approaches to Three Problems

This section poses a problem and then describes how the three archetypes described above could approach solving the problem. Each one is meant to show that none of the problem-solving types is inherently better than the others and that there is no right or wrong way to approach these problems. Instead, these scenarios are meant to show that, due to the nature of the training and problem-solving approaches each archetype utilizes, they are each differently suited to different types of specific situations.

1) Patient A started coughing this morning. What should she do about it?

The Physician: What are the most common causes of cough? What are the deadliest causes of cough? For this patient's age and medical history, which of those causes are most likely? Has she been treated successfully for a cough in the past? Would any test results change the treatment plan? Treatment will be based on what has historically worked best for the most likely diagnosis.

The Engineer: What is different now than when she was not coughing? What was she doing this morning when the cough started? If she tries one treatment and gets a little better, then she should use more of it to get a greater effect.

The Life Scientist: If it is infectious, what is causing the infection? If we find what is causing the infection, do we know how it is causing the cough or irritation?

In this case, the physician probably has the fastest and most efficient route to diagnosis and treatment plan if there is a common cause for the cough. The life scientist's method, when it eventually gets to a treatment, will have produced a lot of information, but it would take a longer time and be very resource-intensive. However, if there is an uncommon cause for the cough, the life scientist's method will be more likely to find it. The engineer's

method could work as well but does not use the shortcuts of the physician or the robust strategy of the scientist.

2) Patient B had her gallbladder removed by Dr. C. Dr. C performs a laparoscopic procedure, but the tools she uses do not work the way she wants them to and she feels that she spends too much time struggling with the equipment rather than performing the procedure. Other surgeons say they have the same problem too. What should be done?

The Physician: What have other surgeons done to compensate for the unwieldy tools? Do any of those methods fix the problem of taking too much time struggling with equipment?

The Engineer: What exactly does the surgeon like and dislike about the system? How could we modify the current system to keep the benefits and lose the difficulties?

The Life Scientist: How would we, from first principles, design a novel laparoscopic system that does not have those problems?

For this issue, the engineer probably has the most efficient approach. Rather than starting from scratch like the life scientist, or treating the problem as fixed like the physician, the engineer's approach looks for the simplest novel solution using the current context.

3) Patients D, E, F, G and H all have a form of slow-growing cancer that no one has seen before. The patients are all related, but they do not carry any of the genetic mutations known to be associated with other cancers. What type of therapy should be used for patients with this disease?

The Physician: Of all the cancer types known, which one is the closest to this one? How is that cancer treated? If that does not work, what is the next closest match? How is that cancer treated?

The Engineer: What makes this cancer different than the closest match that has been treated in the past? Can we use that difference to modify the treatment plan?

The Life Scientist: How does this cancer work? What genetic mutations and/or environmental factors are driving the cancer cells to proliferate? Can

that information be used to determine how to selectively kill the cancer cells without harming healthy cells within the patient?

In this case, because there exists very little information about the problem itself, the life scientist's method is probably the best approach "scientifically" to take for identifying a long-term plan for treating patients with this disease. However, the physician's method arrives at a treatment faster, but it is more uncertain and may cause more pain and discomfort with less overall benefit if the closest analogy has a very different root cause. The engineer method looks at these differences to try to find a solution.

Three Forms of Failure Analysis

Another important difference in training and practice between the three archetypes is how they approach failure analysis. Failure analysis is more of an introspective skill set than problem solving or design, one that entails a different set of biases. Something possibly went wrong, and the task is to find the error, adding a dimension of responsibility that the above discussion of problem solving does not necessarily entail. The assumptions of personal accountability and responsibility differ among the archetypes, and this can affect how they each approach problems or reviews of another group's performance. Especially in multi-disciplinary endeavors where multiple teams and individuals are responsible for different system components, defending the decisions leading to an error can be an important consideration when contemplating a new approach or idea. How will they defend this decision to peers and outside reviewers if things do not go well? Moreover, in what environment will they be defending it? Much like problem solving, understanding the differing approaches to failure analysis can improve collaboration and prevent misunderstandings that are likely to occur when reviewing errors or outcomes in a multi-disciplinary group.

The Physician: When physicians talk about failure or mishaps formally, it is usually in a meeting called "Morbidity and Mortality" (M&M). The M&M is considered so important to the medical profession that the Accreditation Council for Graduate Medical Education (ACGME), the organization responsible for accrediting medical residency programs in the United States, requires M&M sessions to be held regularly during a physician's training. In an ideal M&M meeting, a case that resulted in an undesired outcome is presented to the entire medical staff of a department or organization. Then the

group will ask questions of the responsible staff to try to determine whether the outcome was avoidable and, if so, where the fault lies. Many states specifically[1] exempt these meetings from being used to determine legal liability, emphasizing that the purpose of an M&M is not assignment of blame, but rather quality control and education. In these meetings, blame is often assigned and also often accepted during peer group discussions. While the precise M&M meeting interpersonal dynamics depend on the level of respect within the group, an accusatory atmosphere is typically prevented through a baseline assumption of physician competence. In contrast to the other two groups, physicians are usually more likely to give their colleagues the benefit of the doubt. The questions raised during these sessions are highly collaborative in tone, and participants often precede their queries with a statement that they do not know what they would have done differently in the same situation. However, this approach can be limiting to new ideas. Often it is easier to defend a choice if it followed the standard of care, even if that choice was objectively worse for the patient.

The Engineer: Once again, the engineer functions somewhat midway between the physician and the life scientist. Though the nomenclature differs between industries and organizations, most engineering groups have some form of weekly or monthly "incident reviews" (see inset). In these meetings, "failure" can mean anything from a catastrophic collapse of a whole system to a validation test in which some components performed outside of specifications. In contrast to the engineer's approach to problem solving, here, the engineering group is focused on finding the root cause of the error. Often, a no-fault approach is used to facilitate individuals to speak up without fear of blame. In systems involving human users, many engineers are trained to follow a "Swiss cheese" model of fault analysis. In this model, the engineer acknowledges that it is rarely one error that causes a failure, but rather, several errors, each from a different source, typically align to allow the failure to occur. The underlying assumption of this model is that failure is inevitably going to occur at some point, so it is not appropriate to level all the blame for failure at the final fault

Other names are Lessons Learned, Fault Tree Analysis, Wishbone, or Root Cause Analysis depending on the method used. Ironically, engineers in the non-medical field often call them "Postmortems."

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1 Connecticut's Medical Liability laws (*https://www.cga.ct.gov/current/pub/chap_368a.htm#sec_19a-17b*) (Accessed July 20, 2017).

when all the precipitating errors are to blame as well. In these meetings, like physicians, engineers assign responsibility but not blame. Like life scientists, they are interested in the root cause of a failure and do not begin with an assumption of competence. However, as mentioned, in the engineer's formulation, it is not necessarily the fault of an individual if they did not exhibit competence in a given situation. In these incident reviews, meetings are usually kept orderly by a top-down approach, and it is considered the responsibility of the program manager or system engineer to prevent the meetings from becoming acrimonious.

The Life Scientist: Most scientific groups have some variation of a weekly "lab meeting." In these small group sessions, a group member will often present some in-progress project or recent data. Confusing results and unexpected data are presented, with the hope that the group can provide technical support, mechanistic insights, or advice for future experiments. If the results are unexpected, it is common to question whether the experiments were performed properly and if all the appropriate controls were conducted to establish the validity of the tests. Here, the questioners often do not assume the competence of the presenter without data to support that the techniques were properly executed. This is one form of "peer review"—or the quality control process that occurs in science. In fact, the motto of the United Kingdom's Royal Society is "*Nullius in verba*,"[2] which roughly translates to, "does not take anyone's word for it," including your closest colleagues'. These meetings can become very heated, but what, theoretically, stops someone from being too confrontational is that they know they must stand in front of the same group at some point in the future and present their own data. That said, most academic scientists can usually tell you a story of a lab meeting where someone went too far and a graduate student or postdoctoral fellow was found crying in a cubicle later.

The differing methods in failure analysis can often be seen in the question-and-answer sessions following presentations at large national meetings, which is where a lot of physicians, engineers, and life scientists first encounter one another outside of their working groups. Anecdotally, questions at engineering conferences tend to be more confrontational than at medical conferences, but less confrontational than at scientific conferences. While these meetings do not constitute failure analysis, the peer-review aspect of such meetings renders the tone of questioning critical at times, and discussion tends to follow the framework of each archetype's trained method.

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2 Royal Society (*http://royalsociety.org/about-us/history*) (Accessed July 20, 2017).

Archetype Vernacular Guide

Understanding the differences in problem solving and failure analysis is important for a broad view of how the different archetypes can think differently. One specific way in which these differences manifest is when physicians, engineers, and life scientists use the same words to mean very different things. Clearly, this can lead to confusion and misunderstandings. In the examples below, each term is followed by the meaning of a common use of the term according to each archetype and then an example sentence for context.

Test:
    Physician: examination of symptoms or disease presence
        He was tested for high blood pressure.

    Engineer: determination of limits
        The beam was tested to failure.

    Scientist: experimentation to obtain evidence in support of a hypothesis
        The protein-membrane interaction hypothesis was tested.

Risk:
    Physician: effect of pre-existing factors on chance of disease
        His risk of heart disease is increased by his father's death from heart attack.

    Engineer: probability of a particular outcome
        The risk of structural failure of this beam at 30 lbs. is 80%.

Result:
    Physician: presence or absence of disease or condition
        The results of the CT scan show a pulmonary embolism.

    Engineer: capabilities of a design
        The results show the wing can provide lift without structural failure from 50 to 300 mph.

    Scientist: experimental evidence
        Our results show that the protein interacts with the membrane.

Failure:

Physician: unsuccessful treatment
   The blood pressure medicine failed to prevent a heart attack.

Engineer: exceeded limitations
   The beam failed at 40 lbs.

Scientist: unexpected findings or technical difficulties
   The protein-membrane experiment failed to support the hypothesis.

   The experiment failed due to incorrect salt concentrations in the buffer.

We hope that the above discussion will help inform future discussions among physicians, engineers, and life scientists. As each field continues to train and practice in their own paradigms, there will continue to be differing approaches to problem solving, failure analysis and even basic vocabulary. However, appropriate recognition and use of these differing approaches by management and collaborators can lead to a more thorough common understanding and robust solutions by multi-disciplinary teams.

5

Risk Analysis and Acceptance: A Model Ethical Framework

David Liskowsky, PhD

Abstract: NASA has adopted a novel ethical decision-making framework to guide risk acceptance decisions in cases where it is known that an established health, medical, or performance standard cannot be met for a proposed mission scenario. The framework is based on guidance provided in a report from the National Academies' Institute of Medicine, requested by NASA, to address this situation. The details of the ethical decision-making framework are provided, as are the steps NASA has taken to implement it. Additionally, the possible use of the framework in realms other than health, medicine, and performance are discussed.

Keywords: standards, risk analysis, risk acceptance, decision-making, ethical principles, ethical responsibilities

Introduction

Current planning for long duration space missions, including exploration missions to Mars, will likely expose crews to levels of known risks beyond those allowed by current medical, health, and performance standards. An example is radiation exposure, where the duration of a planned Mars mission scenario may result in all crewmembers possibly exceeding the established radiation exposure limit standard, without any effective engineering or operational means of lessening the exposure. Not being able to meet the standard will result in an increased health risk for the crewmembers. In such a case, the questions of how to proceed regarding implementing the mission, move from engineering and operational design solutions, into the realm of policy and ethical decision-making. Such questions include:

- When is it, if ever, appropriate to knowingly accept a higher level of risk and not meet an established standard?
- What are the policy and ethical factors that need to be considered in making such a decision?
- Are there policy and ethical criteria that need to be met in order to justify the decision to not meet an established standard?
- What are the roles, responsibilities, and rights of the various parties (i.e., crewmembers, mission planners, Agency administrators) that would be involved in such decision-making?

In order to address this somewhat novel and vexing issue, NASA's Office of the Chief Health and Medical Officer (OCHMO), which is the responsible NASA office for medical, health, and performance standards, engaged the National Academies' Institute of Medicine (IOM) (now the National Academy of Medicine) to conduct a study to examine policy and ethical issues relevant to crew medical, health, and performance standards for exploration and long duration space missions. In particular, NASA asked for guidance regarding a possible framework of ethical and policy principles that can help guide decision-making associated with implementing health standards for exploration-class space missions when existing standards cannot be fully met, or the level of knowledge of a given condition is sufficiently limited that an adequate standard cannot be developed, for the mission. The IOM established an Ad Hoc Committee on Ethics Principles and Guidelines for Health Standards for Long Duration and Exploration Space flights. Some of the key questions the Committee addressed were:

1. What ethical considerations are involved in developing and implementing health and safety standards for manned space exploration when the exposures and risks are uncertain, unknown, and/or when exposures and risks might exceed current standards?
2. What standards of informed consent regarding the health risks of the mission are appropriate, and what are the ethical limits of informed consent processes in these circumstances? What principles should be applied (when relevant) to communicating the uncertainty regarding health risks?
3. What are appropriate modifiers for standards for protecting individuals when there is an incomplete understanding and knowledge of the potential risks or hazardous exposures, or when exposures and risks may exceed current standards?
4. Should all astronauts and space flight crewmembers be protected to the same risk level or should potential individual differences be considered? Would one standard be sufficient for the entire space flight crew or do known or unknown differences in risk need to be addressed to provide a uniform level of protection?

The report "Health Standards for Long Duration and Exploration Space flight: Ethics Principles, Responsibilities, and Decision Framework" was released by the Committee on April 2, 2014. This chapter describes the key aspects of the report and the ethical principles and responsibilities described in it, and how NASA has incorporated them into its health and medical standards processes and decision-making.

Background: Medical, Health, and Performance Standards

Similar to the engineering and safety aspects of space flight, human space flight involves a high degree of risk to human health and performance. These risks include both short term health consequences in flight (e.g., space motion sickness, alterations in blood pressure regulation upon return to Earth) and long-term health consequences that arise or continue months or years post-flight (e.g., radiation-induced cancers, loss of bone mass). If unmitigated, these risks can result in serious decrements in the health of a crewmember, and in some cases, can even be fatal. Additionally, depending on their time course and nature, these unmitigated risks can have an impact on the ability of a crewmember to successfully perform his or her duties during a mission, and/or may have long-term health impacts later on in an individual's

life. The possible acute mission impact effects of the risk, as compared to long term health effects later in life, can be a possible factor in making the determination of what level of risk can and should be accepted in a given mission scenario.

In order to mitigate known human health and performance risks, medical, health, and performance standards (to be termed "health" standards in this chapter), have been developed that have to be met in the development and design of spacecraft and space operations. These standards encompass both human-related engineering design risks, and medical and healthcare risks. The engineering type standards relate to areas such as the design of environmental control systems, human factors engineering, and the control of air and water contaminant exposures, and they are met by appropriate engineering design solutions. Medical care and health issues include standards for the level of medical care to be available on a given class of space mission, and standards that define the acceptable level of decrement or change in the health of an individual that can be allowed. Examples of the latter include the maximal level of bone demineralization or muscle atrophy that are acceptable, and maximum levels of radiation exposure an individual can experience. Bone and muscle loss are examples of space flight induced health changes that could impact the ability of a crewmember to effectively carry out his or her duties during a mission, while radiation exposure is an example of a risk that could have long-term effects beyond the mission. These medical and health standards are met by the development and implementation of medical countermeasures that control the physiological changes of concern (e.g., exercise regimes to maintain bone and muscle strength) or by the establishment of allowable limits for environmental exposures (e.g., radiation exposure).

Policy and Ethical Framework for Decision-Making

"Excepting" a Standard

The IOM Committee first looked at possible options NASA could take if, on a planned human long duration space flight mission, an established health standard could not be met. They considered both the idea of liberalizing the existing health standard so it could be met, and establishing more permissive health standards for long duration and exploration-class missions. In both cases, they determined that there was not an ethically justifiable reason to implement such changes. In the case of liberalizing an existing standard, NASA's health standards are based on the best available data, and are

regularly updated as new information becomes available. To liberalize them outside this established process would be inappropriate and arbitrary. They also felt that there was not a clear and compelling reason for why acceptable risks and levels of uncertainty should be greater for long duration and exploration-class missions than for other human space flight missions, and thus, there was no justification for establishing more liberal standards for such missions.

Having excluded the options of modifying existing standards, the Committee determined that the only ethically acceptable option that could allow for increased risk exposures in the context of long duration and exploration space flights would be granting an exception to existing health standards. The report then provided guidance on the factors and criteria that should be used in making the decision as to whether an exception to an existing standard should be made. The Committee also noted that exceptions to health standards should be considered on a mission-by-mission basis and used in very limited circumstances.

Ethical Principles

The Committee identified a number of ethical principles that NASA should consider and apply when making a decision whether or not to accept additional risk and provide an exception to an existing health standard, for a human space flight mission. The ethical principles are:

- **Avoid harm**—the duty to prevent harm, exercise caution, and remove or mitigate harms that occur. NASA should exhaust all feasible measures to minimize the risks to astronauts from long duration and exploration space flights.
- **Beneficence**—the principle to provide 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, including current and future astronauts and members of society at large.
- **Favorable balance of risk and benefit**—the principle to seek both a favorable and acceptable balance between the risk of harm and potential for benefit.
- **Respect for autonomy**—the principle to ensure 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, that they have all

available information regarding the risks and benefits of the proposed
mission, and that they continue to be apprised of any updates to risk
and benefit information throughout the mission.

- **Fairness**—the principle requires that equals be treated equally, that
  burdens and benefits be distributed fairly, and that 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**—the 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 healthcare
  and protection for astronauts not only during the mission but post-
  flight, including provision of lifetime healthcare for astronauts.

In making the decision as to whether a standard should be "excepted" or
not, all of these principles need to be considered and weighed against each
other. As can be seen from their definition, some of these principles com-
pete with each other. For example, the need to protect crewmembers from
the health risks of space flight and thus "avoid harm," competes with the
principle of "autonomy" in which the crewmembers have the right for self-
determination and to choose the risks they are willing to take. In addition,
in order to achieve a "favorable balance of risk and benefit," the benefits of
the mission, as described in the principle of "beneficence," must be weighed
against the need to "avoid harm."

Consideration of these ethical principles should be done in the context
of various factors and criteria related to the relevant mission. These could
include requirements that the proposed mission be expected to have excep-
tionally great social value; have great time urgency; have expected benefits
that would be widely shared, not only to the space program but to society as
a whole; and that the proposed mission be justified over alternate approaches
to meeting the mission's objectives.

As mentioned above, unlike typical space flight risk analysis decision-
making, which is based solely on engineering and statistical risk analysis and
assessment, the consideration of these ethical principles and how they will
apply in a given situation to guide the decision-making on a standard excep-
tion, represents a combined policy and ethical determination. As will be seen
later in this chapter, this difference was a significant factor in shaping how
NASA implemented this decision-making framework.

Ethical Responsibilities

A critical component of this decision-making framework is the concept that the decision to accept more risk and except a standard brings with it the requirement to meet certain additional responsibilities in order to ethically justify the decision. The Committee identified a series of responsibilities to which NASA is morally obligated, and must meet and implement, if they are to accept the additional risk of granting an exception to a standard for a space flight mission. These responsibilities are:

- **Informed decision-making:** Fully inform astronauts about the risks of long duration and exploration space flights and make certain that the process is adequate and appropriate.
- **Continuous learning strategy:** Adhere to continuous learning (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 space flight, as well as from other relevant sources.
- **Independent advice:** 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 in a transparent, fair, and timely manner:** Communicate with all relevant stakeholders (e.g., astronauts, the public) the rationale for, and possible impacts related to any decision about health standards.
- **Equality of opportunity:** Provide equal opportunity for participation in long-duration and exploration space flight to the fullest extent possible.
- **Health screening, surveillance, and care:** Provide preventive long-term health screening and surveillance of astronauts and lifetime healthcare, to protect their health, support ongoing evaluation of health standards, improve mission safety, and reduce risks for current and future astronauts.
- **Privacy and confidentiality:** Develop and apply policies that appropriately and sufficiently protect the privacy and confidentiality of astronaut health data.

These responsibilities directly support the ethical principles that would inform the decision to grant an exception to a standard. In some cases, the responsibilities provide a mechanism to ensure ethical principles are appropriately implemented. For example, the ethical principle of "autonomy," which states that individuals have a right for self-determination, requires the responsibility of establishing a strong and robust process for "informed

decision-making" to ensure potential crewmembers are fully aware of all the risks associated with not meeting a standard so they can decide whether or not to participate. Naturally, participation under these conditions would be strictly voluntary, and there would need to be mechanisms in place to ensure there would not be any negative consequences (e.g., career advancement, assignment to future flights) to the crewmember for choosing not to participate. Another example is the ethical principle of "fidelity," which acknowledges that for those who accept additional risk to themselves for the good of society, there is a responsibility to provide them with additional and enhanced health surveillance, screening, and care to address the increased health risk which may occur as a result of not meeting a standard.

Additionally, implementing the responsibilities is mandatory to provide the moral and ethical justification to support the decision to accept the additional risk of granting an exception to a standard. A critical example of this is the responsibility of "continuous learning." The decision to provide an exception to a standard would occur when it is known that there is not an engineering or operational design solution to meet the standard at the time critical decisions about mission planning must occur. In order to morally and ethically justify making that decision, there must be a genuine commitment to continue all efforts to gain the knowledge and technical capability to meet the standard in the future. Thus, this decision-making process should never be considered a way to circumvent established standards and requirements, but rather, it would be a temporary, stopgap mechanism for addressing a critical issue that is imposed by unavoidable mission planning circumstances and conditions.

Framework

Based on the guidance provided in the IOM report, a three-tiered framework of decision-making was developed. The first and broadest decision is whether, and under what conditions, any missions that are unlikely to meet current health standards are ethically acceptable. If it is decided that missions that fail to meet existing health standards are not acceptable, then such missions must be deferred until new knowledge about risk or uncertainties, and risk mitigation strategies, are available. On the other hand, if it is decided that such missions are acceptable, then this ethically based framework should be used, and the criteria and processes to support its use developed. The second level of decision-making is the mission-by-mission decision, using the framework of whether an exception to a health standard should be granted for a specific proposed mission. Finally, the third level of decision-making relates to decisions about the participation of individual crewmembers for

whom, because of unique factors and circumstances, a standard cannot be met if they were to participate in a proposed mission. This differs from the second level of decision-making where it is known that a given standard cannot be met for anyone who would participate in a mission.

NASA Implementation of the Framework

In order to implement the IOM's guidance, the decision-making framework and its associated processes had to be constructed in a way that is compatible with NASA's program/project management structure and how risk assessment decisions are made during mission planning and development. At the same time, it had to recognize that the analysis and decisions associated with the framework are of a policy and ethical nature, rather than engineering and operational. In order to make the first decision of whether the Agency felt it was proper and wanted to implement this ethically based decision-making framework, a proposal to do so was presented to the Agency by the OCHMO at the Agency-wide Program Management Council (PMC). The decision was made that such a framework would be an important component of the Agency's risk analysis and mission planning processes and that it should be developed and implemented.

It was decided that implementing the process should begin with a risk analysis by the Agency medical authorities of the acute and long-term health risks associated with not meeting a health standard, as well as the impact that could have on the ability of crewmembers to successfully carry out their responsibilities. This initial medical risk assessment would then be coupled with the standard engineering and safety risk analyses to obtain a global risk assessment for a proposed mission. The global risk assessment would then be forwarded to Agency senior management.

It was decided that the nature of the policy and ethical decision-making associated with this framework necessitated that it be elevated to the level of Agency senior management. The consideration of such factors and making the decision to accept a known, unmitigated risk should be done at that level rather than being conducted at the level of mission implementation. Agency senior management would then consider the ethical and policy factors of the framework and make a determination of how to proceed. Conducting the analysis at this level would also allow the appropriate involvement of, and communication with, all relevant stakeholders (e.g., crewmembers, mission planners, external parties). This would be the case for either a decision related to a specific mission or the participation of an individual in a given mission.

The key actions and responsibilities that are necessary to support evaluating an exception to a health standard are:

1. Ensuring all feasible means are taken to reduce astronauts' risk to the lowest achievable level and demonstrating that the standard cannot be met despite having done so.
2. Examining all approaches to minimizing risk, including alternate approaches to meeting mission objectives.
3. Thoroughly monitoring and conducting research on health impacts during and after space flight to inform current and future missions.
4. Having a rigorous process to assure astronauts are fully informed about risks and unknowns.
5. Ensuring that a crewmember's decision to participate in a mission meets standards of informed decision-making and that they are making a voluntary decision.
6. Committing to the future health of current and future astronauts by ensuring access to long-term healthcare, longitudinal medical follow-up, and preventative screenings.

If the decision is made to provide an exception to a health standard for either a specific mission or an individual participating in a mission, it would not be a medical "waiver," but rather, an "operational exception" under the authority of the NASA Administrator or their designee. Thus, in this situation, it is recognized that an established and valid medical standard is not being met, and the decision is an administrative one rather than medical.

The specific details of the processes and steps associated with the ethical decision-making framework are codified in the NASA requirements document NPR 8900.1 NASA Health and Medical Requirements for Human Space Exploration.

Conclusion and Discussion

Historically, Agency risk analyses, particularly in the engineering and safety realms, are made using statistically based probabilistic risk assessments. Then, based on that statistical result, a decision is made regarding risk acceptance. The implementation of this ethics-based decision-making framework related to health standards provides NASA with a mechanism that incorporates factors and considerations that typically are not part of the Agency's risk assessment decision-making processes. This allows risk acceptance

decision-making related to health and performance issues to be carried out in a broader context than that provided by statistical analysis alone. If the decision is made to accept additional risk, the framework provides mechanisms and courses of action the Agency should take to support the decision to proceed. The structure of the framework acknowledges the additional responsibilities the Agency incurs by accepting a higher level of risk and allows the Agency to better explain and justify the decision.

Risk decision-making associated with medical, health, and performance issues is well suited to the incorporation of ethical principles and responsibilities. Making decisions to accept risk that can affect an individual's health or medical condition, by its nature, has an ethical and moral component involving the ethical principles and responsibilities that have been discussed. However, the decision-making framework that has been implemented for health standards could also be considered for use in other risk analysis decision-making, and the same principles and responsibilities applied in the safety and engineering realms as well. As with health standards, this would provide a broader context for that decision-making, and result in a stronger foundation to support the acceptance of higher risk levels, particularly in situations where mitigation strategies are not available. While not typically associated with engineering and safety principles, incorporation of a role for ethical considerations in such risk analysis could ultimately result in more far-reaching mission planning and management.

6

Human Systems Integration in Non-Human Space Flight Systems

David Fuller, BS

Abstract: This chapter illustrates how Human Systems Integration (HSI) applies to all of NASA's systems. From design, operation, and sustainment of large complex facilities such as wind tunnels and thermos-vacuum chambers to seemingly mundane systems that help maintain security at the gate, HSI can reduce risk of injury and mission failure.

Introduction

Effective planning and implementation of Human Systems Integration (HSI) practice in NASA systems should be addressed in all of NASA's systems, including non-human space flight (HSF) projects such as deep space and Earth observation satellites, sounding rockets, balloons, Unmanned Aerial Systems (UAS), and robotic exploration missions. Ground systems and test facilities, such as thermal-vacuum chambers, wind tunnels, and mission operations centers, can also be considered complex systems that would benefit from the use of HSI during all phases of the project life cycle.

HSI processes are described in detail in a previous chapter, but it is worth emphasizing that all of the complex systems mentioned in the above paragraph are operated, maintained, and repaired by humans. Without considering the role of the human in the system life cycle, as early as possible, risk of human casualty, mission failure, and added costs and schedule delay are increased.

Currently, NASA Procedural Requirements (NPRs) and NASA Policy Directives (NPDs) regarding non-HSF projects have little or no language that addresses human factors or HSI considerations. NASA requirements pertaining to facilities and facility systems safety deal mainly with developing and executing contracts with vendors. Usually a vendor will specify "industry best practices" in their proposal and design or implement these practices as part of the statement of work.

Federal and state laws and regulations related to safety and worker protection are followed at all NASA centers and facilities. These regulations, however, do not explicitly address human factors associated with, for example, reliance on the human operator to correctly interpret data and make a decision that might have an undesired outcome.

Maintainability is another subset of HSI that is usually not addressed by federal or state regulation. There are examples from many industries of mishaps that occurred due to a system design that made maintenance and inspection difficult. When a process is difficult or time-consuming to perform and organizational pressure is exerted to perform procedures as fast as possible, procedures are often performed with forgotten, or even purposefully skipped, steps.

Poor maintainability design also leads to workers being injured while trying to perform their tasks. Recently, this author observed an inspection of a home furnace that required connecting pressure gauges to the refrigerant lines. The connection point could have been placed on an easily accessible front panel. Instead, the manufacturer chose to place the connection points

in a space that was not only difficult to reach, but impossible to view. A consequence of this design decision has led to many minor cold burns by refrigerant gas because of technicians inadvertently hitting a pressure relief valve while they were reaching up into the space to connect the test device. This example of industry practice indicates that not all practices are necessarily good just because that is the way it has always been done.

Examples of NASA Mishaps and Close Calls in Non-Human Space Flight Systems

The NASA Mishap Investigation System (NMIS) has many examples of mishaps and close calls that illustrate how HSI might have prevented loss of money, loss of prestige, injury, and morbidity and mortality. It is, of course, impossible to prove that HSI would have prevented these incidents, but it is certain that an HSI practitioner, providing a human factors perception, would have reduced the risk of these mishaps taking place.

Example 1: Solar Dynamics Observatory High Gain Antenna Subsystem 2 Damage

Spacecraft systems go through thermal vacuum (TVac) to ensure that the flight systems will perform to specification in the extreme environments found in orbit. A process called Bake Out is also performed to reduce outgassing and potential contamination of components and systems prior to flight.

TVac test of the Solar Dynamic Observatory (SDO) High Gain Antenna Subsystem (HGAS) 2 took place in late November 2007, after the successful completion of the HGAS 1. During the holiday break, the Bake Out portion was suspended, to be resumed after personnel returned.

During the break, the application that provided temperature information to the heater control function was deactivated after an operating system (OS) update on the test system computer. The Bake Out operation was restarted by an operator that had not been involved with the earlier testing. The temperature information application that had been stopped during the OS update was not restarted, and the heater control system ran in an open loop configuration. The HGAS 2 components reached temperatures above 150°C, severely damaging the HGAS 2, and required repairs of approximately $990,000.

The SDO HGAS TVac and Bake Out test control system was a design unique to the SDO project, and facility operators were not aware of the need

to restart the temperature information application, and no instructions or procedures had been written for this unique test configuration.

The Mishap Investigation Board (MIB) found that root causes included deficient test planning and operational procedures and inadequate personnel training.

Example 2: Wallops Flight Facility Runway Incursion Close Call

In June 2015, a U.S. Navy P-3 Orion aircraft conducted a touch-and-go maneuver at the Wallops Flight Facility (WFF) airfield. Touch-and-go maneuvers are routine training exercises performed by flight crews to maintain flight proficiency. The U.S. Navy regularly conducts training exercises at WFF because of its close proximity to one of its bases.

At the time the P-3 was on final approach to the runway, an airport truck was making a routine periodic inspection of the runway, looking for foreign object debris (FOD) that could damage the aircraft.

All movement on the runways and taxiways of an airport with a control tower are coordinated by the airport tower. The tower at WFF was not staffed in the evenings, and the airfield would revert to a process whereby airfield flight activities were coordinated among the users via the Universal Communications (UNICOM) radio procedures. At WFF, UNICOM radio traffic advisories are handled by the WFF Protective Services Dispatch Office.

The Mishap Investigation Team (MIT) report cited a root cause as the Protective Services contract did not include specialized training for UNICOM operations for their security officers. This lack of training led to inadequate communications and handover procedures, which resulted in the P-3 aircraft conducting a touch-and-go maneuver while an inspection truck was on the runway.

Example 3: Glenn Research Center Main Gate Barrier

In June 2011, a mishap occurred in which a Glenn Research Center (GRC) main gate security barrier was activated while a vehicle was moving through the gate, causing damage to the barrier and vehicle and injury to the vehicle passenger. The investigation conducted by the MIT concluded that a number of human factors–related failings contributed to this mishap, including inadequate training, inadequate understanding of the function of the barrier and its safety features, and a last-minute change in standard operating procedures (SOP) of the barrier that was not properly documented and training in the changed SOP was not properly passed on to the security officers that operated the barrier.

This change in SOP failed to consider that the control station for the barrier was designed and placed so that security officers had full view of threats approaching the gate area, and the barrier itself was behind the security officer and therefore out of view.

Other factors that were considered contributory were that the control to raise the barrier did not have a guard to prevent inadvertent activation, and the mishap security guard was working a double shift and might have been fatigued.

In these examples, and in many of the reports contained in the NASA Mishap Information System (NMIS), it is clear that human factors played a significant role in initiating or contributing to the undesired outcome. A review of the project by a qualified HSI practitioner would have been able to perceive these shortcomings and made appropriate recommendations.

Proposed Future Efforts

Changes to NASA policy should never be undertaken without proper research, preparation, and review by all stakeholders. The NASA Safety Center (NSC) maintains a large repository of mishaps and close calls, and a tool called the NMIS that can be used to show the extent of human factors–related events in NASA.

Mishaps and the resulting investigations are considered trailing indicators of organizational safety because they occur after the fact. Important lessons learned can be gleaned from these reports; however, they are limited in that they do not reflect the hundreds of events that occur on a regular basis that do not become mishaps because of human intervention.

A more important, leading indicator of organizational safety is the close call and hazard report. These events can be filed by anyone within the Agency and reflect the day-to-day processes, practices, and concerns of NASA employees.

An analysis of events within NMIS will provide evidence on whether the Agency needs to make changes to the existing policies. Other sources of evidence will be interviews and conversations with the NASA safety professionals in the NSC and field center safety organizations, facility management organizations, and system safety organizations.

Assuming that evidence supports further work, a good example of developing HSI requirements at the program and project level can be found in the development of NPR 7123.1B and the latest update of the NASA Systems Engineering Handbook, SP-6105.

Complex systems, regardless of whether they are flight systems, wind tunnels, thermal vacuum chambers, or security systems, must be designed with human operation in mind. Formulating Agency-level policy will provide a uniform implementation of HSI within all programs and projects within the Agency.

<center>7</center>

The NASA Human System Risk Mitigation Cycle: Standards to Requirements to Deliverables

<center>*David R. Francisco, PhD*</center>

Abstract: With over 50 years of human space flight experience, NASA has gathered medical, environmental, and research evidence to assess the effects of the hazards of space flight on the human body. Historically, NASA utilized groups of subject matter experts to assess individual risks, but as mission complexities increased, it was realized that the traditional approach to assessing and researching the mitigations for the human risks of space flight were not adequate. In order to maximize the understanding of this evidence and mitigate these human system risks, a tailored methodology was developed to assess the space flight evidence and quantify the risks. A key requirement of this new approach was the ability to weigh the risks relative to each other so that effective tradeoffs can be made to ensure that an optimized set of medical capabilities are on each mission. This chapter describes the risk methodology implemented by NASA to assess the evidence regarding the effects of the hazards of space flight on astronauts and potential mitigations.

Keywords: human system risk assessment, hazards of space flight, evidence, performance, health, risk mitigations

Introduction

With over 50 years of human space flight experience, NASA has gathered medical, environmental, and research evidence to assess the effects of the hazards of space flight on the human body. Even though NASA has been flying for nearly 60 years, there are fewer than 600 individuals that have flown in space, and this limited number of subjects makes it very challenging to fully characterize and understand the effect of the hazards of space flight on humans. Historically, NASA utilized groups of subject matter experts (SMEs) to assess individual risks, but as mission complexities increased, it was realized that the traditional approach to assessing and researching the mitigations for the human risks of space flight was not adequate. In the context of health, hazard is any source of danger to the health of the crew, and this implies a threat; a threat is a factor that can affect health status; and risk is an undesirable health outcome with an increased probability of morbidity and/or mortality. The confluence of hazards and threats equal risk.

In order to maximize the understanding of this evidence and to mitigate these human system risks, a tailored methodology was developed to assess the space flight evidence and quantify the risks. A key requirement of this new approach was the ability to weigh the risks relative to each other so that effective tradeoffs could be made to ensure that an optimized set of medical capabilities were on the mission. It was also imperative to ensure that research related to mitigating these risks was especially focused on risks with the highest consequence and likelihood of occurrence. This process needs to include understanding the hazards of space flight and gathering, assessing, and correlating evidence to better predict the probability of the event occurring and the consequence of the event on human health and productivity. This strategy also includes standardized assessment of space flight human system risks and development of human space flight medical standards and requirements for spacecraft vehicle developers to ensure that the best possible risk mitigations are in place, while utilizing minimal resources. In order to implement this process, a cross-discipline board, the Human System Risk Board (HSRB), was formed that includes SMEs in the fields of Medical Operations (flight surgeons and biomedical operations), Occupational Health, Research/Science, Environmental Sciences, Epidemiology, and Safety Mission Assurance and Engineering.

Human System Risk Board

The HSRB is the NASA Health and Medical Technical Authority (HMTA) control board that implements and maintains a consistent, integrated process for assessing and managing the Office of the Chief Health and Medical Officer (OCHMO) human system risks.

The HSRB:

1. Identifies and analyzes human system risks and concerns;
2. Endorses cross-program, multidisciplinary action plans to mitigate risks and understand concerns;
3. Tracks the overall progress of the action plans developed and implemented by the programs (funding entities);
4. Determines risk dispositions ("mitigated with existing countermeasures" or "requires additional countermeasures for mitigation") to identify forward work and to ultimately establish a risk posture per Design Reference Mission (DRM) characteristics;
5. Reviews and approves risk-related topics entailing updates to NASA Standard 3001 volumes, transition to operations technologies, and other potential issues that may change an already established risk posture;
6. Establishes HMTA positions for technical items required for future programs; and
7. Disseminates risk status and the latest human system risk knowledge to human space flight programs, other NASA organizations at Johnson Space Center (JSC), Headquarters (HQ), other centers, and to other stakeholders to review all human system risks, establish a comprehensive risk management and configuration management plan, and enable medical and research data sharing. These major developments of standards, the HRP, the HMTA, and a forum for review of human system risks, Human System Risk Board (HSRB) facilitated the integration of human research, medical operations, systems engineering, and many other disciplines in the comprehensive review of human system risks.

The HSRB assesses human system risks based on five main hazards that challenge the health and performance of flight crews during space missions: Altered Gravity, Radiation, Isolation, Hostile/Closed Environment, and Distance from Earth.

Hazards of Space Flight (Hazard + Threat = Risk)

Risks associated with human space flight are influenced by a variety of factors including vehicle design, distance from Earth—which drives the required medical capabilities—behavioral health due to isolation (affected by mission duration, vehicle design, and distance from Earth), the gravity environment during habitation/transit, gravity transitions during landing and takeoff, and the radiation environment. These hazards, coupled with the duration of the mission, drive the human risk for each mission. For this tailored methodology, six design reference missions were developed to encompass the majority of space flight missions that NASA is considering. These design reference missions were chosen because of "natural" breakpoints of the hazards that affect human risks. These natural breakpoints factored the changes in radiation environment from low Earth orbit (protection of the Van Allen Belts) to deep space radiation galactic cosmic rays (GCRs), duration for return to Earth which drives the amount of medical care capabilities on the vehicles, gravity environment and factors required for vehicle design (especially environmental system/life support). **Table 7.1** provides an overview of DRMs and space flight hazards.

Evidence-based assessments are performed for six design reference missions: (1) low Earth orbit, (2) six and 12 months, (3) deep space sorties (30 days), (4) lunar habitation for one year, (5) deep space habitation for one year, and (6) planetary/celestial body transit and habitation for three years.

Evidence Assessment

Evidence is gathered from numerous sources to understand the effects of space flight hazards on humans. These sources include (1) astronaut medical, research, and occupational data with space flight exposures; (2) space flight environmental and operational data; and (3) terrestrial medical and research data, including analogs and ground-based research. Outcomes based on the space flight human data must be correlated with the environmental and operational data acquired from existing missions, and then it must be extrapolated to future missions with different conditions. This environmental data includes such factors as carbon dioxide levels on the vehicle, radiation levels, duration in microgravity, and exposures and acoustic levels during the mission.

Table 7.1. Design reference missions and the hazards of space flight.

| Design Reference Mission	Mission Duration	Vehicle/Habitat Design	Hazards of Space Flight			
			Distance from Earth/ Earth Return	Isolation	Gravity Environment	Radiation Environment
Low Earth Orbit	6 months	Midsized Volume Resupply	LEO—240 miles Ground Control	1 day or less	Microgravity	Low Earth Orbit Within Van Allen Belts
Low Earth Orbit	1 year	Mid-Large Optimized Volume Resupply	LEO—240 miles Ground Control	1 day or less	Microgravity	Low Earth Orbit Within Van Allen Belts
Deep Space Sortie	1 month	Small Volume, Self-contained, Closed Loop Environment	300,000 miles Ground Control	< 5 days	Microgravity	Deep Space
Lunar Visit or Habitation	1 year	Mid-Large Optimized Volume Limited Resupply	240,000 miles Semi-autonomous	5 days	Microgravity	Lunar
Deep Space Journey/ Habitation	1 year	Mid-sized Optimized Volume Limited Resupply Closed Loop Environment	200,000–34 million miles Complete Autonomy	Weeks to months	Microgravity	Deep Space
Planetary	3 years	Mid-sized Optimized Volume No Resupply Closed Loop Environment	34 million miles Complete Autonomy	Months	Microgravity $3/8$ g	Deep Space Planetary
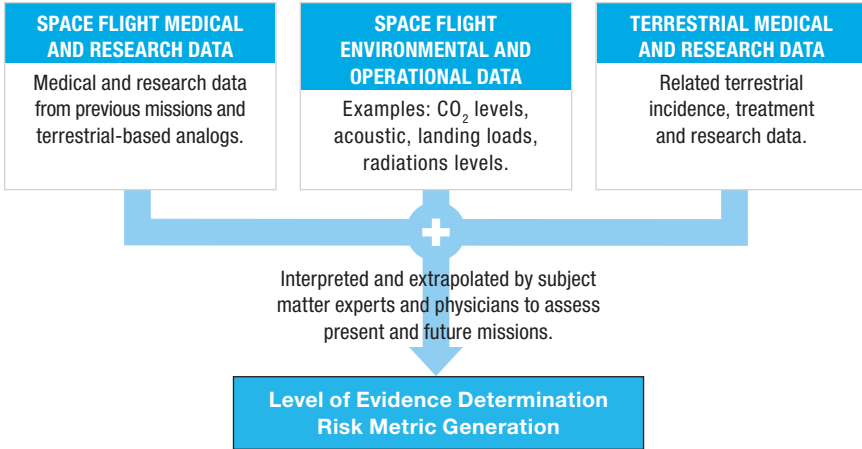
FIGURE 7.1. Evidence sources and interpretation.

For example, the radiation assessment evidence is gathered from terrestrial radiation accidents and animal models and is interpreted and extrapolated to the space environment to predict the consequence to humans (**Figure 7.1**). This interpretation and extrapolation (space radiation has a different makeup from terrestrial gamma radiation) has large uncertainties which limit the ability to fully quantify the risk.

Based on assessment of all evidence from all sources, 100 medical conditions and outcomes were considered to be the most likely that need to be considered for mitigation during space flight. The probability of the event occurring and the severity of the outcome were considered by interpreting all levels of evidence and utilizing SME to extrapolate to future missions with different hazards. Refer to for a list of these medical conditions and outcomes in alphabetical order.

1. Abdominal Injury
2. Abdominal Wall Hernia
3. Abnormal Uterine Bleeding
4. Acute Arthritis
5. Acute Cholecystitis/ Biliary Colic
6. Acute Compartment Syndrome
7. Acute Diverticulitis
8. Acute Glaucoma
9. Acute Pancreatitis
10. Acute Prostatitis
11. Acute Radiation Syndrome
12. Acute Sinusitis
13. Aerobic Capacity Loss
14. Allergic Reaction (mild to moderate)
15. Altitude Sickness/ Hypoxia
16. Angina/Myocardial Infarction
17. Anaphylaxis
18. Ankle Sprain/Strain
19. Anxiety
20. Appendicitis
21. Atrial Fibrillation/Flutter
22. Back Injury
23. Back Pain (SAS)*
24. Barotrauma (sinus block)
25. Behavioral Emergency
26. Burns secondary to Fire
27. Cardiogenic Shock secondary to Infarction
28. Chest Injury
29. Choking/Obstructed Airway
30. CO_2 Headache/ICP/ Cognitive
31. Constipation (SAS)
32. Decompression Sickness Secondaryto EVA

33. Dental: Exposed Pulp, Caries, abscess, tooth filling/crown loss
34. Depression
35. Diarrhea
36. Dust Exposure (Celestial)
37. Elbow Dislocation
38. Elbow Sprain/Strain
39. Electric Shock Injury*
40. Eye Abrasion (foreign body)
41. Eye Chemical Burn
42. Eye Corneal Ulcer
43. Eye Infection
44. Eye Penetration (foreign body)
45. Finger Dislocation
46. Fingernail Delamination (EVA)
47. Gastroenteritis
48. Head Injury
49. Headache (Late, SAS)
50. Hearing Loss*
51. Hemorrhoids
52. Herpes Zoster
53. Hip Sprain/Strain
54. Hip/Proximal Femur Fracture
55. Hypertension
56. Immune System Dysfunction/Illness
57. Indigestion
58. Influenza
59. Insomnia
60. Knee Sprain/Strain
61. Landing Loads/Injuries
62. Lower Extremity Stress Fracture
63. Lumbar Spine Fracture
64. Malnutrition
65. Microbial-Host Interaction
66. Medication Overdose/ Reaction

67. Mouth Ulcer
68. Muscle Atrophy
69. Nasal Congestion (SAS)
70. Nephrolithiasis (renal stone)
71. Neurogenic Shock
72. Nose bleed (SAS)
73. Orthostatic Intolerance*
74. Otitis Media/Externa
75. Paresthesia
76. Pharyngitis
77. Respiratory Infection
78. Retinal Detachment
79. Seizures
80. Sepsis
81. Shoulder Dislocation
82. Shoulder Sprain/Strain – EVA
83. Skin Abrasion, laceration
84. Skin Infection
85. Skin Rash
86. Small Bowel Obstruction
87. Smoke Inhalation
88. Space Motion Sickness/ Neurovestibular
89. Stroke (CVA)
90. Sunlight Exposure/ Sunburn*
91. Sudden Cardiac Arrest
92. Toxic Exposure: Ammonia+
93. Traumatic Hypovolemic Shock
94. Urinary Incontinence (SAS)
95. Urinary Retention (SAS)
96. Urinary Tract Infection
97. Vaginal Yeast Infection
98. VIIIP – Visual Impairment/Increased lntracranial Pressure
99. Wrist Fracture
100. Wrist Sprain/Strain

Figure 7.2. The 100 considered space flight medical conditions and outcomes in alphabetical order. Conditions/risks listed with a red number are exacerbated or caused by the hazards of space flight and are detailed in Figure 7.3.

Assessment of the One Hundred Medical Conditions and Outcomes

In order to assess all of the medical conditions, a standardized process was developed to ensure that each condition was assessed consistently and that results could be compared across all conditions. After the initial review, the conditions that were driven by the hazards of space flight were separated from the conditions that were just part of "being human." This separation allowed for those conditions that were not exacerbated by space flight to be lumped together and mitigated through medical screening and the application of traditional terrestrial medical care.

After the review, it was determined that 30 conditions/risks were exacerbated or caused by the hazards of space flight, and those conditions were assigned individual human space flight risks and were assessed in more detail. Refer to **Figure 7.3** for a list of the conditions/risks driven/influenced by the hazards of space flight.

Likelihood and Consequence of a Risk

The process used to assess these risks utilizes likelihood of the event occurring coupled with the consequence of the event. The assessment factors include all countermeasures to the risk that include three distinctive phases: (1) selection factors that can be assessed/modified pre-mission such as screening criteria, pre-flight treatment and training; (2) design factors such as duration, location, and countermeasures suite that can be implemented; and (3) post-flight treatment and reconditioning. See **Figure 7.4** for a graphic of the generic types of factors for risk mitigation and a radiation example for the three phases of countermeasures.

The likelihood and consequence are considered with known countermeasures implemented, and, if for some reason countermeasures cannot be implemented, the risk assessment is recalculated to reflect the actual countermeasures being implemented. For example, the likelihood of renal stone formation goes up with less water consumption and higher bone loss, so if water consumption is limited, the likelihood would change and the risk posture would be reassessed.
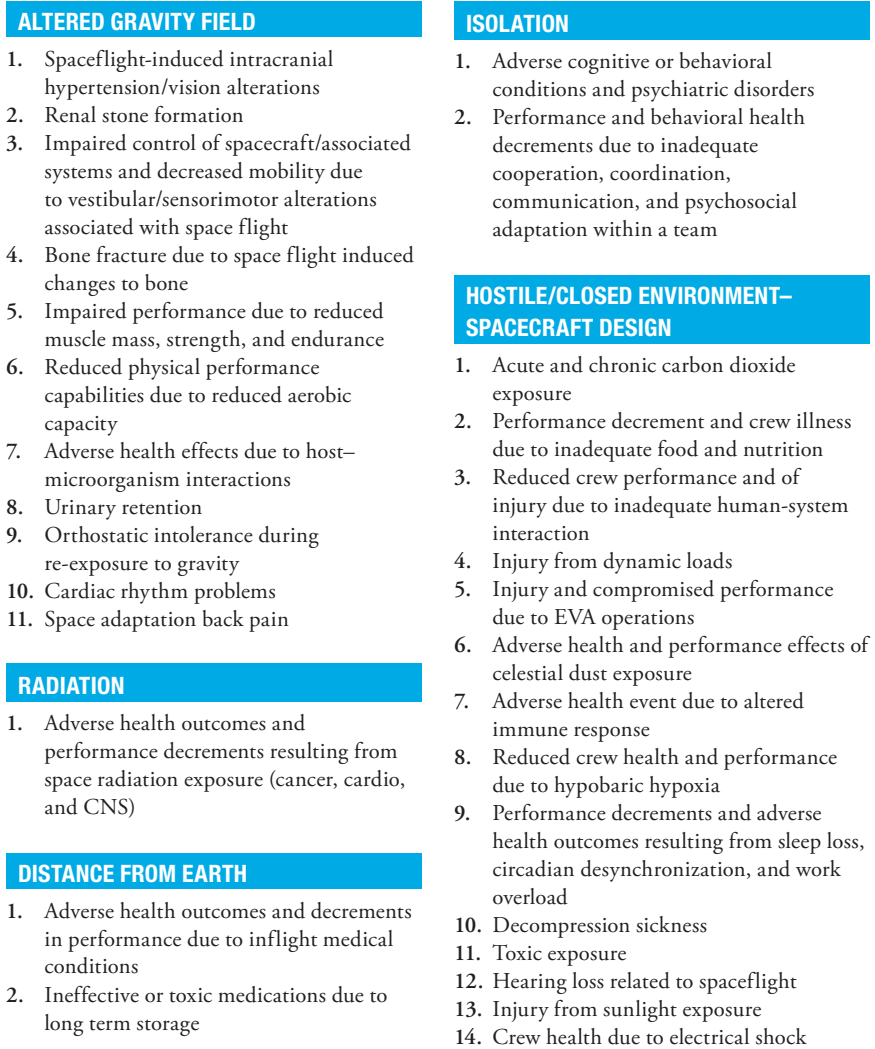
ALTERED GRAVITY FIELD

1. Spaceflight-induced intracranial hypertension/vision alterations
2. Renal stone formation
3. Impaired control of spacecraft/associated systems and decreased mobility due to vestibular/sensorimotor alterations associated with space flight
4. Bone fracture due to space flight induced changes to bone
5. Impaired performance due to reduced muscle mass, strength, and endurance
6. Reduced physical performance capabilities due to reduced aerobic capacity
7. Adverse health effects due to host–microorganism interactions
8. Urinary retention
9. Orthostatic intolerance during re-exposure to gravity
10. Cardiac rhythm problems
11. Space adaptation back pain

RADIATION

1. Adverse health outcomes and performance decrements resulting from space radiation exposure (cancer, cardio, and CNS)

DISTANCE FROM EARTH

1. Adverse health outcomes and decrements in performance due to inflight medical conditions
2. Ineffective or toxic medications due to long term storage

ISOLATION

1. Adverse cognitive or behavioral conditions and psychiatric disorders
2. Performance and behavioral health decrements due to inadequate cooperation, coordination, communication, and psychosocial adaptation within a team

HOSTILE/CLOSED ENVIRONMENT–SPACECRAFT DESIGN

1. Acute and chronic carbon dioxide exposure
2. Performance decrement and crew illness due to inadequate food and nutrition
3. Reduced crew performance and of injury due to inadequate human-system interaction
4. Injury from dynamic loads
5. Injury and compromised performance due to EVA operations
6. Adverse health and performance effects of celestial dust exposure
7. Adverse health event due to altered immune response
8. Reduced crew health and performance due to hypobaric hypoxia
9. Performance decrements and adverse health outcomes resulting from sleep loss, circadian desynchronization, and work overload
10. Decompression sickness
11. Toxic exposure
12. Hearing loss related to spaceflight
13. Injury from sunlight exposure
14. Crew health due to electrical shock

FIGURE 7.3. Thirty human system space flight risks that are influenced by the hazards of space flight beyond normal terrestrial standards.

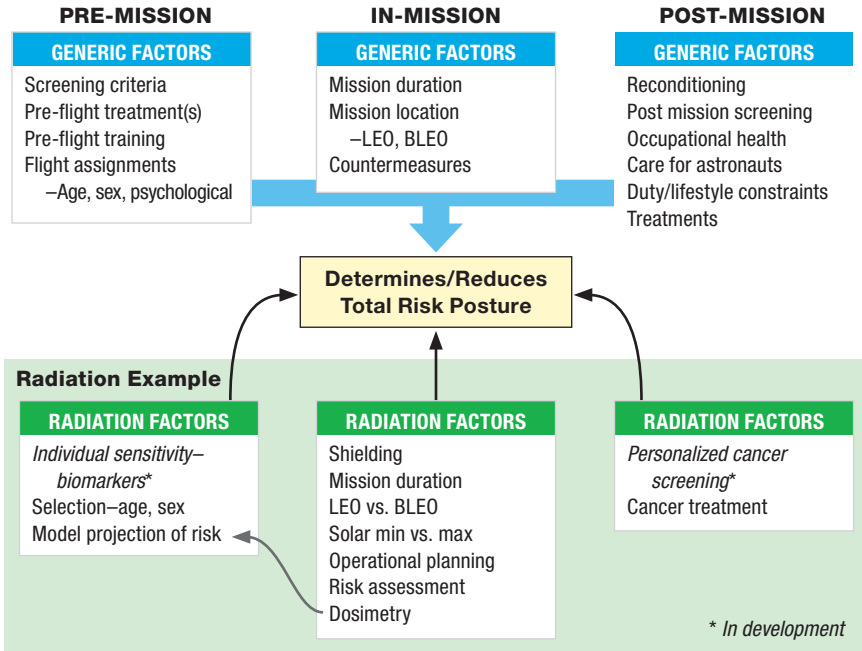**FIGURE 7.4.** Factors that influence risk countermeasures.

Likelihood Assessment

The human risk assessment utilizes a 3×4 matrix that has three levels of likelihood and four levels of consequence (see **Figure 7.5**). The three likelihood levels of the human risk occurring are: (1) Low, < 0.1%, which is for events that have a very low probability of occurring but the consequence may be significant; (2) Medium, > 0.1 and < 1%; or (3) High > 1.0%. One percent was chosen for the controlling likelihood based on the "1 percent rule," often utilized in aviation, that limits the risk of medical incapacitation to less than 1% in a given year. The likelihood is determined for both in-flight health and productivity and for long-term impacts (post-flight).

	Low	Medium	High
High	1 x 4	2 x 4	3 x 4
Medium	1 x 3	2 x 3	3 x 3
Low	1 x 2	2 x 2	3 x 2
Very Low	1 x 1	2 x 1	3 x 1

Consequence Mission Health and Performance (OPS)

Death or permanently disabling injury to one or more crew (LOC)
OR
Severe reduction of performance that results in loss of most mission objectives (LOM)

Significant injury, illness, or incapacitation—may affect personal safety
OR
Significant reduction in performance results in the loss of some mission objectives

Minor injury/illness that is self-limiting
OR
Minor impact to performance and operations—requires additional resources (time, consumables)

Temporary discomfort
OR
Insignificant impact to performance and operations—*no* additional resources required

Consequence Long Term Health (post mission) (LTH)

- Unknown and improbable return to baseline (requires drastic intervention surgery and therapy)
- Major impact on quality of life (permanent reduced function, premature death)

- Return to *near* baseline requires extended medical intervention with known clinical methods, technologies (pharmaceuticals, etc.)
- Moderate impact on quality of life

- Return to baseline values within 1 year with nominal intervention (time, exercise, nutrition, lenses)
- Negligible effect on quality of life

- Return to baseline values within 3 months with *limited* intervention
- No effect on the quality of life

Likelihood
Low ≤0.1% Medium <1% High ≥1.0%

CM = Countermeasure
LOC = Loss of Crew
LOM = Loss of Mission

Quality of Life is defined as impact on day-to-day physical and mental functional capability and/or lifetime loss of years.

FIGURE 7.5. Likelihood and consequence matrix for human system risk assessment.

In-flight Health and Performance Consequence Definitions

Coupled with the likelihood calculation, in-flight health and performance consequence is divided into 4 categories: (1) very low, which is described as a temporary discomfort that does not impact performance; (2) low, which is described as a minor injury that is self-limiting, requiring minor medical intervention; (3) medium, which is a significant injury that has a significant reduction in performance and requires significant medical intervention; and (4) high, which is permanently disabling injury or death.

Long-Term Health Consequence Definitions

Long-term health consequence is also divided into four categories: (1) very low, which is described as having no effect on quality of life and the astronaut returns to baseline within three months post-flight with limited intervention such as an exercise program; (2) low, which is described as having negligible effect on quality of life, such as the astronaut returning to baseline values one year post-flight with nominal intervention such as nutrition or corrective lenses, or such as bone mineral density returning to pre-flight values with nominal exercise and nutrition or correction of vision with lenses; (3) medium, which is described as having a moderate impact on the quality of life; and (4) the highest consequence category is classified as having a major impact on quality of life.

Summary

With an established methodology to assess the human risk of space flight, a comprehensive assessment has been made for all of the human risk referenced and is continuously updated based on emerging evidence. These risk assessments are communicated to program managers, engineers, and researchers to enable present and future NASA human space flight missions.

8

The Integrated Medical Model:
A Case Study in Communication

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Abstract: One of the main challenges NASA faces is the communication difficulty of two disparate entities, engineers and human system experts in life sciences, with completely different backgrounds. A manifestation of NASA's attempt to bridge that communication gap is the development of the Integrated Medical Model over the last decade. Engineers use probabilistic risk assessment models to inform their own risk analysis; the medical community as a part of human systems integration has worked to develop a tool that expresses medical risk in quantitative terms that are relatable to and interpretable by engineers. Cataloging the approach, the challenges in the development of this tool, and its subsequent implementation is the focus of this chapter.

Keywords: space flight risk communication, NASA hazard analysis, engineering, medical, human systems integration, probabilistic risk assessment, integrated medical model

Introduction

NASA's Engineering-centric History

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 has only recently begun to recognize this insufficiency and to reach out to communities, both domestic and international, to gain expertise on how to remedy it.[1]

NASA has historically had a primary engineering focus dealing with the operation of aircraft and spacecraft; the science of flight; and the study, design, and manufacturing of machines capable of flight, leaving the human system risk as a secondary consideration. From early space flight through the current day, the assumption has been that NASA buys down the risk of failure of the human system through rigorous selection of individuals designed to minimize medical issues and optimize available capability in flight. The inherent assumption has been that risk of vehicle system malfunction far outweighs the risk of human system failure. As space flight increases in duration and distance from Earth, the validity of this assumption is repeatedly challenged and a formal quantitative merger of the medical assessment of risk with the engineering characterization becomes increasingly valuable. The implication of this re-evaluation is that, under current practices, the human system is not given due significance as part of systems integration in the risk trade space of NASA space flight, even decades after its founding. The importance of human systems integration (HSI) will only increase:

> Exploratory missions with humans involve a high degree of human-machine interaction. The human factor will become more important as the durations of missions into deep space with humans increase and as the spacecraft crew functions more autonomously, adapts to unexpected situations, and makes real-time decisions.[2]

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1 "Safe Passage: Astronaut Care for Exploration Missions," Washington, DC: National Academy Press, 2001.

2 Ibid.

Medical Risk:
A Component of Human Systems Integration

Medical risk as a component of the HSI problem has been addressed by other government agencies. While not a NASA-specific problem, NASA's needs are unique and the approaches taken by other agencies require some tailoring. Identifying human system components and quantifying associated component risk are required to best assess risk correlated with HSI. The Department of Defense has identified the following seven HSI domains:

1. Human factors engineering
2. Personnel
3. Habitability
4. Manpower
5. Training
6. Safety and occupational health
7. Force protection and survivability

with the goal to "optimize total system performance and total ownership costs while ensuring that the system is designed, operated, and maintained to effectively provide the user with the ability to complete their mission". Although not called out as a domain per se, medical risk is an overarching thread through many of the identified domains above and represents a key component for HSI associated with space flight.

The need for an approach to medical risk prediction has been recognized since the early 1990s; this need led to the current-day Integrated Medical Model (IMM). Medical risk, as with any other risk, is described by a set of three components: (1) scenarios—what events could occur, (2) likelihood—how often can an event occur, and (3) consequence—what happens if the risk event occurs. NASA has used several risk prediction methodologies, including fault tree analysis (FTA), failure modes and effects analysis (FMEA), and probabilistic risk assessment (PRA). During the Apollo era, the General Electric Company provided results of a NASA-commissioned PRA using an FTA approach; this study predicted a less than 5% chance that NASA would successfully land a man on the moon and return him to Earth. Following the release of this report, NASA's approach to risk management shifted from PRA and focused instead on design-oriented techniques (e.g., FMEA, Critical Items List application), which continued for several decades. It was not until the 1986 Space Shuttle Challenger accident that NASA fully recognized the vital importance of employing a risk prediction strategy that

takes into account complex systems. Following this mishap, NASA began employing PRA strategy more prevalently, with a focus on risk prediction of Space Shuttle Program activities. Medical risk as a human system component of NASA's PRA plan evolved over several years, moving from qualitative to quantitative prediction, as described in the following section.

Approach to Medical Risk Assessment

Acknowledging the importance of medical risk as a human system failure, in 1990 NASA assembled a Clinical Experts Seminar with extramural and NASA subject matter experts (SMEs) to discuss medical system risk for the planned Space Station Freedom, including prevention, diagnosis, treatment, and transport aspects of the Health Maintenance Facility (i.e., medical capabilities) for long-term space flight. Potential medical scenarios were discussed along with Classes of Illness definitions, Medical Operations ground network, and medical risk in the context of different crew return capabilities. Results from the Seminar included the recognition that

1. accurate prediction of medical risk was not possible, only estimates;
2. extrapolations of epidemiological data could be misleading with a mismatch of population and/or illness reporting;
3. capabilities, or lack thereof, could have significant impact on medical risk; and
4. the training aspect for in-flight medical care should not be neglected.

Shortly thereafter, a more quantitative approach was taken by employing a risk perception survey that was conducted by medical SMEs in 1993 to improve the characterization of medical risk during space flight. Recognizing the importance of predicting overall medical risk, the questionnaire was directed towards medical events where little to no space flight data existed. Incidence and perception of risk data were compared with analog population, U.S. astronaut, and Soviet cosmonaut data to provide context for these results. These questionnaire results were combined with existing astronaut health data to establish a medical data set for medical risk decision support that included consideration of resource capabilities.

In 1999, the International Space Station (ISS) Program pursued development of a risk prediction PRA model quantifying safety-related risks, including both engineering and medical risks. Although PRA at this time was already in use by NASA engineering to assess risk in other areas, the ISS PRA

model represented one of NASA's first attempts to introduce medical risk as part of human systems integration with vehicle safety concerns. The medical data set developed above provided the basis for the ISS PRA model calculation of the probabilities associated with loss of crew life (LOCL) or consideration of evacuation of a crewmember (EVAC), key end states of the ISS PRA model. The biggest flaw with this approach was that although medical risk was recognized as an important component of quantifying safety-related risks in the ISS PRA model, the medical data set used by the model was still based largely on SME opinion rather than a more quantifiable evidence-based approach.

> What are we to do when the irresistible force of the need to offer clinical advice meets with the immovable object of flawed evidence? All we can do is our best: give the advice, but alert the advisees to the flaws in the evidence on which it is based.

A more evidence-based approach with quantification was needed to predict medical risk within the context of larger mission risk. The IMM became the quantified evidence-based solution (described below). When results from the IMM were initially compared with those from the ISS PRA model, the probabilities associated with LOCL and EVAC were higher by almost an order of magnitude (**Figure 8.1**). Given NASA's lessons learned in prior human mishaps and almost two decades of engineering application of PRA, why had PRA methods not been applied to medical risk prediction before this point? A central issue is the requirement to provide a valid process for understanding and interpreting medical evidence in the context of PRA-specific implementation to represent medical risk. The next sections describe several aspects of the technical challenges in implementation that led to this delay, and the unique HSI complexities posed in using traditionally engineering-based methodology.

Challenges and Implementation

Medical Risk Quantification Challenges

Assimilating the vast information needed to determine space flight medical risk presents an enormous challenge that led to the initial underestimation of the probability of key end states by SMEs. Accurate estimations of end state values require quality evidence-based data for the above three components of risk (i.e., scenarios, likelihood, and consequence). NASA collects model data
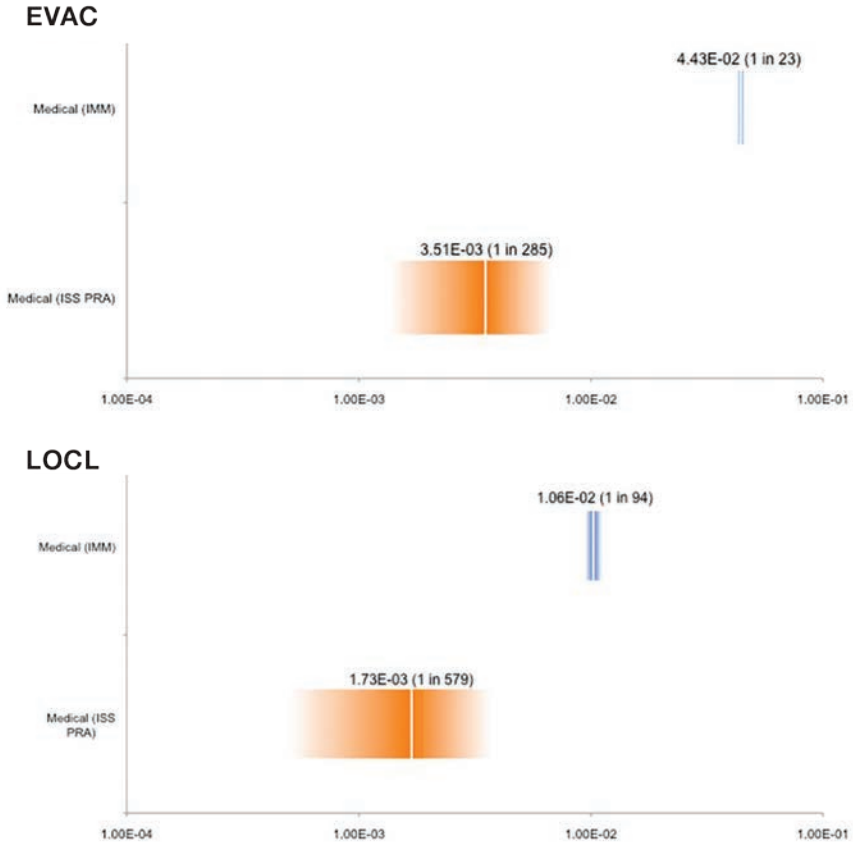
End state outcomes (EVAC = evacuation, LOCL = loss of crew life) from the ISS PRA model (8)
are shown using medical data input from the Integrated Medical Model (IMM) and subject matter
experts (ISS PRA).

Figure 8.1. EVAC and LOCL Probability Values:
ISS PRA Model versus IMM Outcomes (2010).

needed to support evidence-based numbers for risk calculation in a variety of
ways. A primary limitation in obtaining space flight and space flight analog
data related to medical risk is that these data have not historically been kept
in a single centralized location. Instead, they have been dispersed throughout
the agency in various locations and under various oversight authorities. Even
after their compilation, limited space flight data must still be merged with
appropriate analog data, in a traceable manner, to create a requisite data set.
Other difficulties to overcome in obtaining appropriate model data include
levels of evidence (LOE) data interpretation and data translation into the

model, including the appropriate integration of direct space flight data from in-flight crew and use of more abundant, but potentially less-relevant, terrestrial (analog) population data.

As indicated above, required data sets for assessing space flight medical risk are not centralized or co-located; multiple sources need to be considered. This includes giving due consideration to all medical aspects required such that sufficient detail is captured to effectively describe risk for each medical condition. In the case of a medical event, several facets contributing to mission impact must be considered, including condition incidence, event severity, available diagnosis and treatment resources, and unique crewmember attributes from individual past medical history. Integration of this medical event information with terrestrial analog data and unique space flight environmental factors further increases the challenge of estimating mission impact of a single medical event, let alone overall space flight medical risk due to all anticipated medical events. In assessing medical risk, there is a range of effects that a single medical event could have on mission level risk estimates. For example, a single event of a small skin rash has a different mission impact than a cardiac arrest. For total mission medical risk assessment, characterization of multiple different types of medical events and the likelihood of successful diagnosis and treatment all contribute to mission-level quantifiable risk outcomes. These data need to be integrated through an evidence-based assessment of expected incidence, event severity scenarios, and availability of diagnostic and treatment resources of the different medical events culminating in predicted outcomes for mission medical risk as a whole. Each individual piece of medical condition data should only be used after careful consideration of space flight context (if available) as well as the context of terrestrial populations in similar analog environments (e.g., data from submarine crews, military personnel, or adventurists in extreme environments). Collating all of these data sets is necessary to adequately inform any space flight medical model, including the IMM; the quality of each of these data sets is also an important consideration in assessing overall human systems medical risk.

Data quality assessment and translation are complicated but are necessary to appropriately assess overall mission risk. Reference sources associated with a given data set can be characterized by using an LOE scale, where evidence can range from so weak that it is hardly convincing to so strong that no one disputes its correctness. Determining proper context of each source associated with space flight medical risk, which does not follow any typical LOE scale, required defining a new LOE scale (IMM LOE scale described below).

Generally, data are deemed "high quality" if data are considered a good fit for their intended use. In considering HSI, human variability is unavoidable

and represents aleatory uncertainty associated with any piece of data in the prediction of human systems risk. The quality of data sets, however, may be due to a lack of knowledge, described by epistemic uncertainty, which can be reduced by gathering more data or increasing the evidence-based quality of the existing data to better match the astronaut population of interest. Incorporation of aleatory and epistemic uncertainties associated with each contributing medical data component added a new dimension of data translation complexity to the previous approach in quantifying medical risk where the resultant data were expressed primarily as point estimates. The importance of applying a quantitative framework while capturing uncertainty in all aspects of NASA PRA was emphatically stated by the NASA Return to Flight Task Group Final Report following the 2003 Space Shuttle Columbia accident (highlights added):

> Further compounding the modeling challenge is the fact that the models most often used for debris assessment are deterministic, yielding point estimates, without incorporating any measure of uncertainty in the result. *Methods exist to add probabilistic qualities to the deterministic results, but they require knowledge of the statistical distribution of the many variables affecting the outcome.* Typically, the distributions of the "independent" variables would be derived from empirical observation. In the case of space flight, however, empirical evidence is often limited or non-existent, so theoretical or engineering distributions must be substituted. *The probabilistic analysis therefore is very dependent on the quality of the assumptions made by the developers.* Although they evaluated some of the assumptions used by the model developers, the NASA Engineering and Safety Center (NESC) end-to-end "peer review" primarily analyzed whether the output of one model could be incorporated into the next, not the joint probability associated with any given output … without which it is difficult to know the reliability of the result.

> Probability distributions are analytic methods necessary when assessing risk. *Without an understanding of the likelihood of an outcome, risk acceptance is a judgment based on instinct and experience. But, as the Columbia accident showed, in a high-risk environment that involves many unknowns like human space flight, experience and instinct are poor substitutes for careful analysis of uncertainty.* This requires that analytical models be used appropriately to inform decisions within a rigorous engineering process.

This represented an additional conceptual shift to the engineering application of PRA in their risk predictions, with a focus on understanding parameter uncertainty. In 2004, NASA's medical community incorporated this same PRA strategy in their development of the IMM to better predict medical risk as a component of mission risk as a whole.

New Approach—Integrated Medical Model

Assessing engineering and medical data and risk to a similar level of granularity and speaking the same risk language are critical, particularly when discussing the total risk posture of a mission and the trade space associated with mission execution. In 2004, conceptual development of the IMM using PRA methodology was initiated as NASA's answer for translating medical data and information into risk language that was understandable to the engineering teams assessing vehicle and mission risk for the agency. An evidence-based approach was used to develop the IMM to ensure that model outputs were valid and that the IMM attained credibility as a risk decision support tool. The IMM uses stochastic processes via Monte Carlo methodology to simulate missions, which consists of three steps. First, input components, consisting of core modeling information and scenario-specific parameters of mission and crewmember characteristics, are specified to define a particular mission profile. Next, the Monte Carlo simulation engine integrates the core and scenario data; medical events, mitigations, and outcomes during the space flight mission are randomly generated based on the pre-defined input values and probability distributions. Finally, the output component depicts the results of the Monte Carlo analysis (with optional optimization of parameters), and total crew health and mission impact outcomes are summarized into quantifiable metrics designed to support mission decision-making and scenario comparisons. Because PRA methodology was already in use by the NASA engineering community, conveying the Human Research Program (HRP) risk, defined as "the inability to adequately treat an ill or injured crewmember," in the context of overall mission safety was effectively communicated to engineering teams using risk components that were already familiar. This communication between the IMM team and various engineering groups was an iterative process, and these sections under New Approach show the challenges and lessons learned of translating medical information, with its inherent uncertainty, into quantifiable figures that engineers understand.

Risk and Risk Components

Whether engineering or medical, risk components associated with PRA answer the following three basic questions:

1. Definition of Scenarios—What can go wrong?
2. Scenario Likelihood—How frequently does it happen?
3. Scenario Consequence—What are the consequences of it happening?

Before assessing "What can go wrong?" for a given mission, the design reference mission (DRM) itself needs to be defined. The engineering concerns of mission duration and the number of extravehicular activities (EVAs) planned can both affect medical risk posture. Similarly, crew composition (number and sex of crew) and individual crew medical attributes (past medical history, such as dental crowns, contact lens use, coronary arterial calcium scores [CAC], history of prior abdominal surgery, etc.) all contribute to the characterization of medical risk to the larger mission parameters. Once the DRM has been delineated, initiating events can be examined as part of the PRA Definition of Scenarios. For the IMM, this means determining potential medical conditions that could occur during the DRM using the IMM Medical Conditions List (IMCL) (**Table 8.1**). Medical conditions in the IMCL occur with a specified incidence and uncertainty. Thus, if a medical event occurs for a given medical condition, the likelihood will always fall within this quantified range. For each condition in the IMCL, an associated Scenario Likelihood is quantified, expressed either as an incidence rate or proportion (**Table 8.1**). The consequence of this event, however, can vary, depending on how an individual responds to the medical event. In the IMM, this follows a best-case or worst-case scenario (**Figure 8.2**) and is dependent on what resources are available to diagnose and treat the event. The event diagram in **Figure 8.2** illustrates potential treatments and outcomes of a single medical event. Scenario Consequences are expressed as end states for each medical event that occurs during the DRM and include the following:

1. resources used to diagnose and treat the event,
2. probability of EVAC (pEVAC),
3. probability of LOCL (pLOCL), and
4. crew health index (CHI) calculated from functional impairments and durations during clinical diagnosis and treatment phases.

TABLE 8.1. IMM risk components.

Definition of Scenarios	Scenario Likelihood Quantification	Scenario Consequence Quantification
What can go wrong?	How frequently does it happen?	What are the consequences?
IMCL	Incidence	End States
Medical condition event 1	Incidence 1 (medical condition 1)	pEVAC 1, pLOCL 1 (medical condition 1)
Medical condition event 2	Incidence 2 (medical condition 2)	pEVAC 2, pLOCL 2 (medical condition 2)
Medical condition event N	Incidence N (medical condition N)	pEVAC N, pLOCL N (medical condition N)

Risk components associated with PRA techniques mapped to elements of the IMM;
IMCL-IMM Medical Conditions List; N = number of events in DR
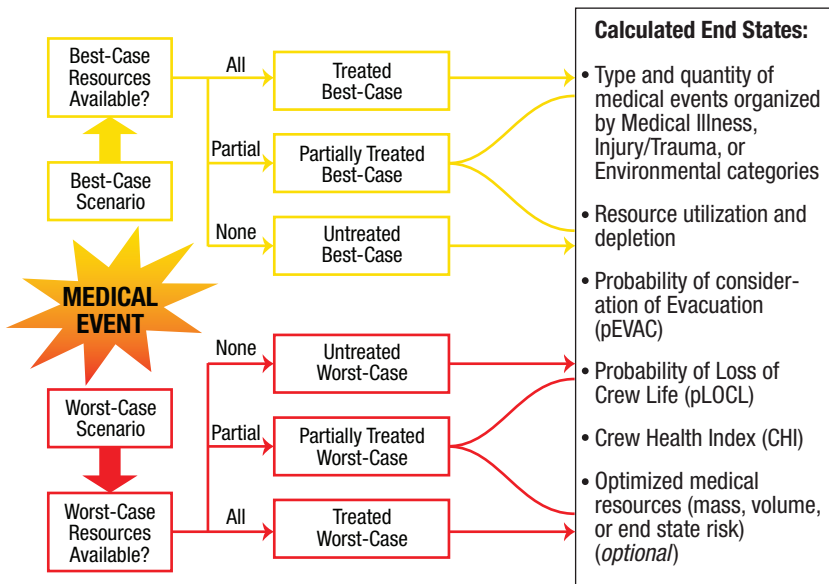
FIGURE 8.2. Medical event flow diagram for best- and worst-case scenarios, considering untreated-treated possibilities with end state outcomes.

End states common to both predictions of medical risk and engineering system risk are shown in **Table 8.1**. End states for the entire DRM are combined, and if desired, medical resources (i.e., trade space) may be optimized by considering "What if?" scenarios to minimize risk or maximize crew health outcomes subject to risk priorities and/or resource constraints to generate new end states. Combined DRM Scenario Consequences are expressed as most likely values with uncertainty distributions and can be integrated directly with engineering results as a component of the prediction of overall system end state risk for a given DRM.

Given an event arising from a medical condition in the IMM database, potential progression pathways are shown for best-case and worst-case scenarios. The best-case scenario is defined as a mild or moderate event requiring minimal or no treatment, typically resulting in more positive end states (i.e., lower resource utilization, pEVAC, pLOCL with higher CHI); the worst-case scenario is defined as a severe event requiring more extensive treatment, typically resulting in less positive end states.

No Centralization or Co-location of Required Data Set

It is important to recognize that several data sets are needed to fully define the manifold risk components associated with quantifying medical risk prediction. Consideration of multifactorial aspects in medicine also takes into consideration the huge diversity of the human system, which contributes to the aleatory (and overall) uncertainty of the model. A rigorous methodology for co-locating information for each medical condition in the IMM was developed and translated into a standardized template, which later was developed into an integrated medical evidence database. Compiled information for each medical condition in the IMM is maintained in a controlled centralized database and includes citations of all source data references used for that given medical condition.

Levels of Evidence Data Interpretation

As discussed above, determining proper context of each reference source associated with space flight medical risk, which does not follow any typical LOE scale, required defining a new LOE scale. Validity and credibility of the IMM are dependent upon the quality of the input data. Space flight missions involve a select astronaut population exposed to an extreme environment that

is isolated, remote, and constrained with limited medical resources, crew medical skills and training, and access to definitive medical care. Therefore, information obtained directly from the astronaut population in the space flight environment is the most relevant input data for the IMM and is assigned the highest level of evidence. The larger the biological deviation from the astronaut population, the greater the model uncertainty will be. Thus, information obtained from terrestrial populations that are analogous to the astronaut population and/or the space flight environment still ranks highly in the LOE scale with decreased epistemic uncertainty in the IMM, as shown in **Table 8.2**. as opposed to data from less comparable terrestrial populations. Given the deviation of the general population from the highly select astronaut population, general population medical information is less relevant as input data for the IMM, introduces additional uncertainty, and subsequently is assigned a lower level of evidence (**Table 8.2**). Additional sources of IMM input data (e.g., input from external models, clinical practice guidelines, and SME opinion) are also shown in the novel IMM space flight medical risk LOE scale (**Table 8.2**). While LOE values do not alter the way the IMM uses evidence from cited reference sources (i.e., higher or lower weighting of the data), LOE information is useful in providing appropriate context to IMM medical conditions by indicating which medical conditions have a sufficiently credible evidence base versus those that are potential targets for additional research.

TABLE 8.2. IMM levels of evidence scale.

Evidence Level	Evidence-based Source
1	Space Flight Data
2	Anecdotal Space Flight Cases Space Flight Engineering Data Validated External Models Terrestrial Data (appropriate analog or cohort, or Bayesian analysis) ISS Medical Check List
3	External Models (not validated) AMA Guides to the Evaluation of Permanent Impairment Clinical Practice Guidelines Standards of Care
4	Terrestrial Data (no appropriate analog or cohort data)
5	SME Opinion

From IMM Approach to LOE (16)

Data Translation

IMM input is comprised of source information as well as end user customer-defined inputs specific to the desired mission to be simulated that the IMM integrates to perform probabilistic forecasts. The IMM utilizes applicable source data, which includes historical data, cohort data, and other applicable medical data sources. For some medical conditions, due to the relative paucity of space flight medical information, Bayesian analysis methods are used with terrestrial analog data to develop estimates of the probability, health effect, and mission impact of medical events during space flight. To the extent possible, all medical information is expressed with applicable uncertainty. Capturing and documenting multifactorial information and data assumptions help clarify the limitations of the IMM. The IMM Monte Carlo simulation component includes algorithms that integrate these source input data and crew mission specifications to generate the IMM output parameters. Each mission simulation runs multiple trials for a given set of parameters. Within each trial of the simulation, medical condition incidence values and likelihoods are sampled to estimate medical event occurrences for the simulated mission. Resource utilization and end states are tracked for each trial. When sufficient trials have been run for the specified mission parameters, a quantitative forecast of the mission and crew health impact is produced by examining the distribution of potential outcomes. To provide necessary context to these IMM results, assumptions and limitations of the model are provided with each IMM report; a summary of IMM assumptions and limitations is shown in **Table 8.3**.

Implementation

After addressing the challenges of translating medical information into quantifiable data that could be modeled with results that engineers could understand, development and testing of conceptual and programmed versions of the IMM could follow. IMM version 1 was a proof-of-concept prototype model version that forecasted mission outcomes for DRMs by applying the PRA modeling process. A formal conceptual model review was held with significant interest from NASA stakeholder groups. Results from IMM version 2 garnered particular attention from the ISS PRA engineering team, particularly after demonstrating the difference in predictions of LOCL and EVAC probabilities using IMM input to the ISS PRA model versus using the prior developed medical data set as input (**Figure 8.1**). This led to formalization

TABLE 8.3. Summary of key IMM assumptions
and limitations and correlating implications.

Simplifying Assumption, Limitations	Implications
All diagnoses are 100% accurate.	Medical resources used and quality time lost due to each medical condition may be underestimated.
All pharmaceuticals maintain maximum efficacy.	Medical resources used, quality time lost, and if applicable, loss of crew and evacuation end state outcomes due to each medical condition may be underestimated.
All medical events receive the appropriate treatment.	Medical resource used, quality time lost, and loss of crew and evacuation end state outcomes (if applicable) due to each medical condition may be underestimated.
All medical events respond to the treatment as expected terrestrially.	Medical resource used, quality time lost, and loss of crew and evacuation end state outcomes (if applicable) due to each medical condition may be underestimated.
All medical equipment is 100% reliable.	For conditions that use powered or calibrated medical equipment for diagnosis and treatment, quality time lost and if applicable, loss of crew and evacuation end state outcomes could be underestimated.
When the status of a crewmember changes to EVAC, only one crewmember is evacuated.	This assumption may significantly underestimate quality time lost during the mission as compared to the real-world ISS where multiple crewmembers would be evacuated if one crewmember was experiencing a medical scenario requiring evacuation.
Most medical conditions, with exceptions including acute radiation syndrome and EVA-linked conditions, occur independently of the occurrence of mission events and other medical conditions. Currently, there is no correlation or association within or between crewmembers for most medical conditions.	The IMM does not currently model the association or correlation among crewmembers of either infectious diseases or an environmental condition (e.g., ammonia exposure); if included, quality time lost and resource utilization associated with correlating conditions would differ from their uncorrelated values.

(continued)

TABLE 8.3 (continued)

Simplifying Assumption, Limitations	Implications
The model assumes another crewmember is available to act as caregiver but does not track the time impact of providing this care.	This assumption may result in underestimating time lost from the mission compared to the real-world system.
Medical procedures are accurately followed and successful; no mistakes occur in executing medical procedures.	This assumption likely results in underestimating of resource utilization, quality time lost, and evacuation and loss of crew end state outcomes.
Crew medical skill level, and preflight and in-flight training, is not modeled.	Medical resources used and quality time lost due to each medical condition may be underestimated.
IMM assumes ISS power, potable water, and oxygen resources are always available in unlimited supply.	Medical conditions requiring these limited vehicle resources may be treated more often in the IMM than in the real-world system, resulting in potentially underestimating quality time lost, evacuation and loss of crew life associated with these medical conditions.

of the IMM, including compilation of requisite model documentation and presentations to several NASA review boards, as a transition to operational use tool for medical risk decision support as part of human system integration into NASA's engineering domain. Ongoing internal and external verification and validation were carried out as part of process improvement during continued IMM development, culminating in a formal external review. A more mature version 4 of the IMM transitioned to operations in 2017 for continued support as a PRA decision support tool for a variety of space flight communities. The IMM has become an integral part of the engineering PRA teams at NASA, helping to inform medical risk assessments for the ISS and Multi-Purpose Crew Vehicle (MPCV) Programs, as well as Commercial Crew Program (CCP) entities.

Use of PRA techniques in both medical and engineering communities facilitated better communication between the two groups, improved understanding of the risks associated in each domain, and developed an enhanced appreciation of the assumptions behind the applied methodology (summarized in **Table 8.3**). This was particularly helpful in interactions with the ISS PRA engineers, and these newly found understandings led to updates

and refinements of both the engineering and medical models after the IMM transitioned to operational use. The following sections describe specific IMM applications with the engineers on the ISS PRA team and the MPCV Cross Program PRA team (XPRAT).

ISS Program

An intrinsic tenet of the IMM is its baseline to ISS medical capabilities and the ISS space flight environment; thus, the ISS Program was a logical starting place to initiate discussions with ISS PRA engineers. Comparison of key mission risk predictions common to both engineering and medical groups with their underlying evidence base and assumptions and limitations led the ISS PRA team to recognize the immense efforts of the IMM team to establish quantitative results with a traceable high-quality pedigree. Comparison of IMM outputs of EVAC and LOCL probabilities to empirical historical space flight data and analog population data provided further validation that IMM outputs were reasonable estimates of the real-world system. In 2010, the IMM team was invited to participate in the then-ongoing evaluation of ISS return vehicle options, culminating in a presentation to the ISS Program Manager. During this presentation, directed questions about IMM results were possible because, as an Aerospace Engineer, these medical model results were communicated in terms familiar to an engineer. As an ISS Manager needing to understand criticality and priority of medical risk information, discussions led to further refinement of the IMM end state consequence of the probability of EVAC into emergent[3] and non-emergent categories that are still a part of the IMM today. Further, having the same risk language enabled the IMM team to have a better understanding of engineering PRA results, leading to discussions between the medical and engineering groups regarding best model input data as well as potential for double counting risks between the two models. These considerations led to further collaboration between the two groups to use the extensive engineering expertise of the ISS PRA team in the realm of FTA of fire and toxic exposure of ammonia aboard the ISS to inform elements of IMM medical conditions associated with these environmental hazards.

Thus, results from the Fire Model component of the ISS PRA safety model were used to more accurately update the IMM with respect to

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3 Emergent EVAC–evacuation required within 24 hours of the onset of the medical event.

operational aspects of smoke inhalation, burns associated with fire, and ammonia toxicity, and the medical risk associated with these IMM medical conditions were backed out of the ISS PRA Fire Model to avoid "double booking" these risks. As another example, the importance of considering HSI in prioritizing vehicle consumable resources was shown when the ISS PRA engineers requested the IMM team to provide a quantitative assessment of supplemental medical oxygen use during six- and twelve-month ISS missions. IMM results were included as part of the decision support package to move oxygen resupply to the ISS to a higher priority. The alliance between the engineering ISS PRA and medical IMM teams is ongoing, with recurrent information exchange between the two groups and systematic updates to the ISS PRA model using IMM results.

Multi-Purpose Crew Vehicle Program

NASA's Health and Medical Technical Authority (HMTA) is required to provide medical risk evaluation to agency Programs while complying with several NASA Procedural Requirements (NPR) including NPR 7120.11: NASA HTMA Implementation and NPR 8900: NASA Health and Medical Requirements for Human Space Exploration. The HMTA in combination with the MPCV XPRAT engineers called upon the IMM to provide MPCV medical kit information with engineering results from five other vehicle design PRA models to assess integrated MPCV mission risk mass and volume trades. The objectives of the MPCV Program are distinct from those of the ISS Program. Consequently, before implementing the IMM, DRM scenarios had to be scoped accordingly to best represent the MPCV system. IMM medical conditions were altered or removed due to the limited MPCV size, shorter mission duration, and absence of planned EVAs. Consultations among engineers from the XPRAT and ISS PRA teams with IMM team members led to adjusting ISS PRA Fire Model inputs to account for the single-compartment MPCV versus the multi-module ISS, resulting in further IMM medical condition modifications to better simulate the MPCV DRMs. Once again, common PRA methodology and language with the ability to communicate and foster mutual understanding of model assumptions and limitations led to fruitful meetings with XPRAT engineers and IMM team members in discussing different optimization strategies for potential MPCV medical kits and the corresponding mass and volume trade space results from the IMM.

Initially, it was a surprise to the MPCV HTMA representative that IMM results indicated that the largest MPCV medical kit did not significantly decrease medical risk when compared to the next smaller sized MPCV medical kit. When key assumptions were discussed, however (e.g., packaging was not considered as part of the IMM medical kit results), mass and volume medical kit trade space was able to be represented in the appropriate context, leading to acceptance of IMM results by the MPCV HTMA representative with appropriate communication to the MPCV Program manager. The IMM continues to contribute to the HTMA evidence-based, configuration-managed process for informing the risk assessment that HTMA representatives provide to the MPCV and other NASA Programs.

Conclusion

HSI Trade in Risk Space and Risk Communication

The IMM has set a new bar for the expectations of information and data coming from the medical community, driving human system integration into a quantitative domain familiar to engineers. The global intent is not to minimize either medical or vehicle and technology risk alone; the goal is to minimize the system risk overall. **Figure 8.3** shows a notional diagram illustrating a decrease in medical risk as mass and volume on the spacecraft are used to provide increasing medical capability. In a limited resource system, allocation of that space may decrease the medical risk while increasing non-medical risk by taking up space that other systems may need. The resulting total system risk is the summation of medical and non-medical risk with a minimal risk point where the appropriate balance amongst system allocations is struck (indicated by the optimal medical system mass/volume point) and total mission risk is minimized (**Figure 8.3**, Total Risk line). This total mission minimum risk point will likely be shifted from where medical and non-medical risk lines intersect. This is because the slopes of the lines are likely not equal—meaning the amount of risk exchanged for either medical or engineering mass/volume is unlikely to be a linear function. While determining this risk point is an elusive concept to implement practically because of the uncertainties involved in risk quantification, the concept has value in principle in human and engineering systems trades. Excessive emphasis on any one system is likely to increase total mission risk. The most important thing for our crews is that we strive to identify the inflection point for total risk to achieve the lowest total mission risk possible, as shown in the notional risk analysis **Figure 8.3**.
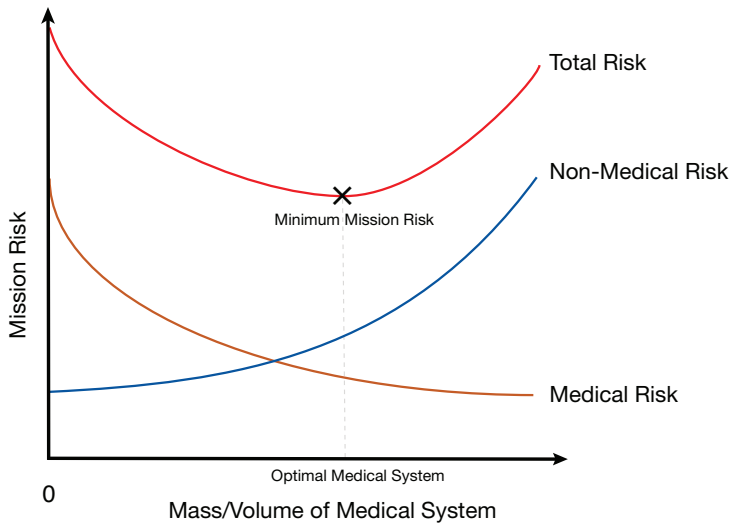
Figure 8.3. Notional mission risk analysis as a function of medical system mass
and volume allocation. *(From Notional Risk Analysis Trade Space.)*

Mission total risk is shown as the summation (Total, in red) of medical (in brown) and non-medical (in blue) risk. As increasing medical capability is provided (shifting the mass and volume trade space towards increasing the onboard medical system), total risk decreases until the point "✕" (minimum mission risk), after which risk from consuming the mass and volume non-medical trade space adds more total risk than what is gained from increasing medical system mass and volume. The minimum mission risk point indicates where the optimal medical system mass and volume trade space occurs (gray vertical dotted line).

In any exploration endeavor, there is a tipping point where high risks of technological failure will give way to human system risks. For NASA, that critical juncture will be reached soon as mission length and distance from Earth both increase. Operations will be forced to change as current capabilities for mission implementation become untenable. These include the lack of ability to use real-time communications with the crew for immediate problem solving or task monitoring, the lack of ability to evacuate crewmembers if they become seriously ill or injured, and the lack of ability to provide resupply for consumable and perishable items such as food and pharmaceuticals. The resulting operational paradigm change will face the challenge of overcoming establishment inertia, as NASA has been an engineering-centric

organization throughout its history. The medical community has risen to new challenges in attempting to quantify information to interface in a meaningful way with the engineering domain. The IMM Project is an example of an ongoing conversation between medical and engineering worlds that makes strides to bridge the gap between training and discipline-approach differences. It is a crucial conversation that the agency must continue going forward. Having a reliable, quantitative approach to changing operational and mission needs will allow the agency to marshal the appropriate resources to minimize total mission risk in the best ways possible to serve our crews and our mission.

Acknowledgments

9

The Human Systems Integration Practitioners Guide

Jennifer Rochlis, PhD, and Elton G. Witt, BS

Abstract: Over the past several years, NASA has been formalizing the approach to Human Systems Integration (HSI) and working to incorporate HSI into existing Systems Engineering (SE) processes. After updating many of our agency-level standards, requirements, and process documents to include HSI content, it was clear that a "user's guide" would be of benefit to encapsulate the philosophy and implementation of its principles. In 2015, the HSI Practitioner's Guide was released, with chapters covering the why, who, when, what, and how. It incorporates best practices and guidance for conducting HSI with an agency-wide perspective and was written in concert with an inter-agency team of HSI experts. It is written primarily for the practitioner, but it also has guidance for managers and discipline experts. Following the NASA SE process, it provides phase-by-phase guidance for activities and products, as well as skills-based tutorials and advice for scaling for HSI activities to any size program or project. Checklists for each SE milestone and a template for writing a program- or project-level HSI Plan is included, along with HSI case-studies, examples, and lessons learned. Since its release, it has been adopted by several projects, including the Multi-Purpose Crew Vehicle Program—NASA's next human-crewed spacecraft.

Keywords: human systems integration, systems engineering, life-cycle costs, domains, practitioner
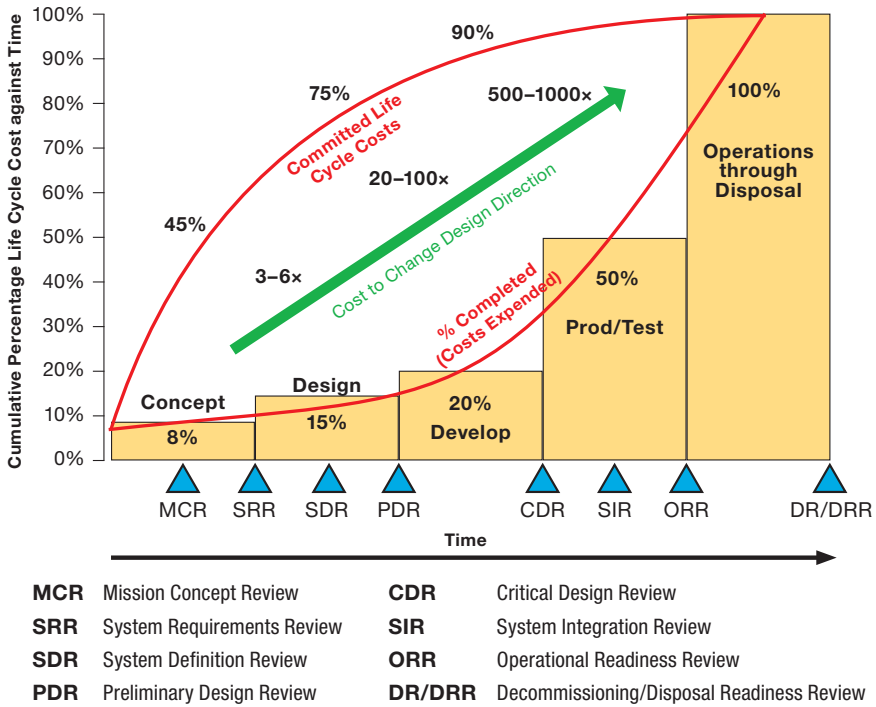
Introduction

What is Human Systems Integration?

Human Systems Integration (HSI) can be defined as an interdisciplinary and comprehensive management and technical process that focuses on the integration of human considerations into the system acquisition and development processes to enhance human system design, reduce life-cycle ownership cost, and optimize total system performance. The human in HSI refers to all personnel involved with a given system, including users, operators, maintainers, assemblers, ground support personnel, logistics suppliers, and personnel trainers. HSI embraces the concept of the human as a subsystem to be treated on par with hardware and software sub-systems. HSI identifies trade-offs across HSI domains and optimizes performance via both physical and non-physical solutions. The end goal is all about capabilities: finding the right set of solutions to meet system objectives.

The Department of Defense (DoD) was the first to identify the need for better design processes for early and thorough consideration of the human element in systems design. They recognized that their unsustainable and escalating lifecycle system costs were due to unanticipated personnel training costs, user interface re-designs, logistics and maintenance expenses, system down time, and repair costs necessary to keep systems operational. It became clear that better design practices for inclusion of the human elements required to develop, deploy, and operate a system were needed, and, in 2003, the DoD mandated that a "total system approach" must apply HSI to all acquisitions "to optimize total system performance (hardware, software, and human), operational effectiveness, and suitability, survivability, safety, and affordability." The DoD states that the goal of HSI is "to optimize total system performance and total ownership costs while ensuring that the system is designed, operated and maintained to effectively provide the user with the ability to complete their mission."

NASA has a well-rooted history of concern for the care and protection of their space flight crews and, as a result, has considered human health and performance in spacecraft and mission design for many years. However, it did have a formal acquisition mandate to include HSI activities in programs and projects until 2012, when updates were made to many of its governing documents such as the Human-Rating Requirements for Space Systems, Space flight Human-System Standards, and Systems Engineering Processes and Requirements.

Significant collaboration between stakeholders is required for successful HSI, and an "early and often" mantra is critical to infusing human concerns

MCR Mission Concept Review	**CDR** Critical Design Review
SRR System Requirements Review	**SIR** System Integration Review
SDR System Definition Review	**ORR** Operational Readiness Review
PDR Preliminary Design Review	**DR/DRR** Decommissioning/Disposal Readiness Review

Adapted from INCOSE-TP-2003-002-04, 2015

FIGURE 9.1. Lifecycle costs are locked in early on in the life cycle.

into all lifecycle phases. **Figure 9.1**, based on a figure from the INCOSE Systems Engineering Handbook (2007), shows that lifecycle costs of a program or project are "locked in" early on. The majority of lifecycle costs (85%) are determined by Phase B of the SE process, and, as time goes on, the cost to make design changes increases to factors of 1,000 times the original design costs. Early adoption of HSI will reduce overall risk and ensure that the system as designed validates its original intent for scope, performance, and mission goals.

Several myths exist around the topic of HSI. One is that the designers intuitively understand the human needs of the system because, after all, they are human. Designers who rely on their own internal human knowledge assume they know all that is needed about the people for whom their system is designed, and such assumptions about human capabilities, individual variation, and how to accommodate for these parameters are at the core of many HSI failures. Another myth is that training is a cost-effective way to work around design shortcomings, whereas in truth, proper designs reduce

the needs for training. Using training as a stopgap measure to solve design problems results in higher operational costs in the development of courses, workarounds, and instructors. A third myth is that adding HSI to a program or project will cost money they do not have. This is a common misconception, which focuses on immediate cost versus lifecycle cost. It is true that HSI inclusion during development may add some initial expense; however, proper application of HSI will result in meeting mission objectives and cost savings in the long run. In fact, early and continuous inclusion of HSI reduces total lifecycle cost, leading to significant reduction of operations costs.

How to Navigate the Practitioner's Guide

The Practitioner's Guide is comprised of four chapters and four appendices. Similar to the previous section, the first chapter outlines "Why HSI" and includes the background and history of HSI, its key concepts, and definitions of the HSI domains. It also contains a use-case table to assist the reader in using the guide whether he or she is knowledgeable in SE (but needs HSI training), knows human factors engineering (but needs SE and HSI training), is working as an HSI practitioner, or is a program or project manager. The second chapter walks through the "Who" of HSI implementation and discusses the authority hierarchy, NASA documentation and required collaborations. The third chapter focuses on the "When" and "What" of performing HSI within the SE framework and provides a phase-by-phase walk-through of products and activities required for each phase. The final chapter presents the practical "How" components, such as getting organized, tailoring methods for different sized programs and projects, planning for HSI, and key skills for the practitioner. The appendices contain annotated outlines of an HSI plan, checklists for the integrator, examples of HSI implementation (with both positive and negative outcomes), and a list of resources.

Throughout the guide, there are a series of explanatory "blue box" examples to help reinforce the content, provide short stories, examples, and additional context (see **Figure 9.2**).

HSI encompasses several domains, or functional areas, against which system trades, studies, and analyses are performed (see **Figure 9.3**). NASA's domains were modified from the DoD framework and include Human Factors Engineering, Operations Resources, Safety, Habitability and Environment, Maintainability and Supportability, and Training. Functional implementation of HSI is based on regular and frequent communication, coordination, and integration across the domains providing human-systems

Emergency Lighting Case Study

During ISS development, a requirement for emergency lighting was established, intended to provide module exit "pathway" illumination during a power outage . The original fielded solution, Emergency Egress Lighting System (EELS), failed to take into account the extensive crew time required to change out the batteries required to keep the system operational. Plus there was extensive logistics for flying up batteries. After many "lost" crew hours, ISS reconsidered, and a second design iteration produced a much more elegant, low-cost and low-impact solution: circular photo-luminescent (glow-in-the-dark) markers, the Emergency Egress Guidance System (EEGS).

In this case study, crew man-hours is used as a cost-equivalent measure. The potential solutions in the second, "experience informed" iteration considered the actual monetary cost of the battery logistics as well. All of the potential design solutions were compared to each other using both the cost- equivalent crew man-hours and the actual cost logistics metric. The selected solution is low-cost for both metrics.

FIGURE 9.2. "Blue Box" example on the Emergency Egress Lighting System.
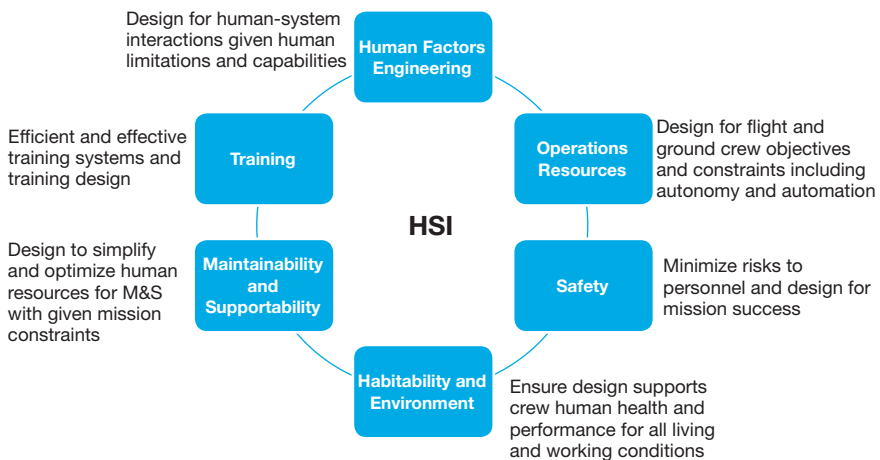

FIGURE 9.3. NASA HSI domain areas.

expertise. Each HSI domain has the potential to affect and interact with the other domains, making it critical to execute an integrated discipline approach. Likewise, trade-off studies typically work to optimize solutions across domains and must include considerations for design solutions as well as non-design solutions. These "non-materiel" solutions, using the DoD term, can also be leveraged to close the capability gap in the form of training, procedures, personnel scheduling, etc. Appendix B contains a checklist with questions for consideration in each of the domain areas to ensure that all domains are addressed in the early development stages.

There are three key components of successfully implementing HSI. The first is having an HSI plan, the second is the HSI team, and the third is the use of metrics to track progress. The HSI plan is a "living" document that outlines the methods by which the program or project will ensure HSI is an integral part of the life cycle. Among other items, goals and deliverables for each phase of the life cycle are defined, as well as relevant methods, tools, requirements, processes, and standards. HSI issues, risks, and mitigation plans are also presented and maintained in the HSI plan.

An HSI Team is comprised of stakeholders, domain experts, and the HSI practitioners. It should be created before the program or project is initiated to help formulate the HSI plan, ensure the plan is implemented, and facilitate resolution of HSI-related issues during the life cycle. The team ensures the most effective, efficient, and affordable design possible through tradeoff studies within and between domains, disciplines, and/or systems. This is not an oversight role as much as it is a collaborative and integrative role, with team members engaging to help solve problems, identify needs for HSI-related domain expertise, and identify human-related cost drivers that could increase lifecycle costs or decrease system performance.

HSI success relies on measurable outcomes. Metrics may include using checklists to track consideration of key HSI-related requirements, cost-equivalent (i.e., crew time or efficiency) measures for task completion, and training time estimates. Conducting HSI domain trade-offs and identification of interactions with other major systems and subsystems can also be tracked.

Conclusion: Keys to a Successful HSI Practice

Programs and projects must acknowledge that the human is as important as other components of the system. To do this properly requires equal emphasis and resources to support HSI. Systems are composed of hardware, software, procedures, and the human, all of which operate within an environment.

When engineers and developers overlook human capabilities and limitations as part of the system design process, the mission goals are put at risk. Trades and analyses must include all personnel that interface with the system, all lifecycle phases, and all expected environments. HSI depends on integration and collaboration of the domain experts and stakeholders towards providing a common basis upon which to make informed decisions. HSI must be considered early and often throughout the design and requirements definition phases. Program managers, project managers, and systems engineers must take ownership of HSI and be held accountable for the outcome. The process must begin with a clear understanding of what the total system (hardware, software, and human) performance requirements are, as well as the mission attributes and goals. HSI requires being equipped with knowledge and tools on how to integrate human performance and capacities into research, design, development, and system implementation, coupled with an understanding of the NASA Systems Engineering Process. NASA is committed to formalizing HSI and providing HSI tools and guidance to all levels of the agency and organizations, towards a sustainable set of programs and projects that meet our nation's exploration, and towards scientific discovery goals.

10

Building Cross-Cultural Bridges for Crew Health and Mission Success

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Abstract: The challenges facing effective human systems integration (HSI) and the consequences of HSI failure to NASA's overall mission success are adequately documented. This manuscript provides examples of attempted use of cross-cultural risk analysis techniques and the use of a common lexicon to enhance communication between different communities of practice to improve HSI. In this final chapter, some of the HSI challenges and failures are summarized, and suggestions to reduce the risks to effective HSI, crew health, and success across all NASA missions are provided.

Keywords: medicine, engineering, complex systems, integration, human factors, HSI, conflict resolution, life sciences research

Introduction

As it relates to human space flight, safe and effective system operations necessitate a synergy between humans and machines, a union of two vastly different systems in a highly and fully integrated final configuration. Biological systems and engineered systems (machines) each are impacted by similar and very diverse laws and challenges. Adaptation of biological systems occurs when the environment changes, whereas the "engineered" system is built to withstand the environmental changes. The differences between the biologic human system and engineered systems (machines) underlie the challenges confronting experts in human health and welfare, human factors, and system engineers. There are significant differences in the medical/life sciences and engineering communities of practice, beginning with the substrate on which each community works, continuing through professional lexicon, risk analysis and identification, to risk remediation and problem resolution.

Examples of Integration Considerations

1. **Differences between living systems and mechanical systems:** Biological systems are inherently diverse. Though similar and consistent at the molecular level, genetic expression drives vast differences between individuals in all species of life. In humans, these differences are expressed from unique appearance to disease susceptibility to cognitive and perceptual processes. As an example, there are over 10 common anatomic configurations of the cystic artery (the blood supply to the gall bladder), and surgeons must be able to identify which configuration they are dealing with when removing a gall bladder. Differences in biology at the cellular and physiologic level are even more profound, driving relatively large parameters in dealing with and accommodating a broad spectrum of individuals. Emotional, cognitive, and behavioral health considerations also drive great variability in higher biologic systems, especially humans.

    This "substrate variability" is usually of less concern in engineered systems, where there is a very high degree of consistency with materials used in construction and few differences between units of production (barring manufacturing tolerances and defects, and assembly and calibration tolerances). Parts are generally freely interchangeable between units in an engineered system, and those units should behave in a very consistent manner. These "substrate" differences affect the respective evidence bases supporting each community of practice and

affect the implementation of actual practice in each community as well. Conceptually, the differences between the engineering and life sciences communities can lead to misunderstanding and misinterpretation, which may lead to unintended consequences. It is highly advisable for these diverse communities to work closely together and understand the concepts of each field to avoid conflict and ensure the development of safe and effective systems to support the common stated programmatic goals.

There is great complexity in the emergent interaction of components in an engineered system, especially in those vehicles and systems that are small in number and unique (such as space flight systems and large wind tunnel facilities). Pilots and operators of complex systems commonly ascribe "personalities" (personification) to the air/spacecraft or systems they are operating, and note that one production unit may well have nuances and performance differences from another. For example, slight variations in manufacturing and assembly tolerances in a fleet of "identical" satellites result in longer training periods for operators and unique maneuver procedures for each vehicle. The complexities that exist in the operations of engineered systems and medical evidence-based practice are in many ways similar, and they might be leveraged to find common ground between these seemingly disparate communities.

2. **Difference in research and development:** Engineering systems design relies on rigorous assessment of resilience, sustainability, usability, manufacturability, failure mode, and probabilistic risk to ensure safety, while biological research relies on repetitive observational or experimental protocols addressing single problems and identification of causal effects. Biomedical research inherently requires long lead-time and is dependent on trial and error. Engineering and technology research is guided by a set of predetermined levels [phases] of readiness. The higher the level, the closer the system is to being ready for operational use. Biomedical research on the other hand tends to lag behind the engineering readiness level and, in many instances, is unable to provide critical design inputs into the engineering systems. This becomes a major source of frustration during tight schedules and budgets.

3. **Differences in approach to fundamental practice:** Engineers design their final products and use uniform materials and components to produce them. Understanding of an engineered system begins with an understanding of the materials used in the system, accounting for manufacturing tolerances, and continues through component parts

assembly and their interaction to produce consistent, desired behaviors and results. Experts in life sciences and medicine are presented a living system intact and must understand it in a retrograde fashion. It has taken centuries for humankind to progress from simple gross observation of living systems to an understanding of cellular physiology and genetics. We are only now beginning to understand how living systems truly work, and our ability to impact and adjust those systems is still rudimentary. From the standpoint of testing and investigation, testing to destruction is accomplished with thoughtful deliberation and regularity in the engineering world. Testing to destruction is highly unethical in the medical world and is not done except at the cellular level (in cell cultures) and in certain lower animal models (at the protest of animal rights advocates). The practical implications are that the communities of practice of engineering and medicine/life sciences approach their disciplines in opposing fashion, again contributing to profound challenges in understanding and cooperation. While biomedical engineering is a bridge discipline, it is more "engineering" centric and is limited in clinical and biological constructs.

4. **Differences in risk analysis and assessment:** The primary engineering risk analysis tool is probabilistic risk assessment, based on modeling and simulations. The evidence base for behavioral, health, and medical risk assessment is based on the epidemiology of health events in populations, which is difficult to apply to any individual due to biologic and cognitive variability. In addition, biological systems adapt to environmental inputs and changes over time. These analytic techniques are both rigorous but very different, even to the lexicons supporting each of them. Understanding the evidence base that supports health and medical risk assessment, which drives system requirements, can be challenging to the engineering community. This can affect the apparent conflicting inputs of health and medical requirements applied to human-operated systems.

5. **The "Aeromedical Factor":** The aeromedical relationship (the relationship between flight surgeons and the population served) is very different from any other clinical relationship in medicine. In the classic clinical relationship between physician and patient, both are working to remediate adverse health issues. The aeromedical relationship properly focuses on the health of crewmembers, but there is also a flight qualification element that crewmembers can perceive as a threat to continuing their flight careers. This dynamic stress between flight surgeon and crew has been active in every aeromedical certification system

for the past 100 years. It is mitigated by firm commitment on the part of flight surgeons to do all possible to preserve health and enable crew-members to continue to fly, but the stigma remains nonetheless. This has probably had a negative overall effect in the relationship between flight medicine and the remainder of the aerospace development and operations community, further widening the communication gulf between the medical/life sciences and engineering communities.

6. **Relationship between oversight authorities and program/project authorities:** NASA has established technical authorities (engineering, safety and mission assurance, health and medical) to provide independent technical oversight in the planning and execution of programs and projects. The technical authorities are less impacted by constraints due to cost and schedule and are meant to enhance safety and program/project overall success. Dynamic tension exists between the technical authorities and program/project management, exacerbated in the case of health and medical technical authority by the differences discussed above.

7. **Organizational challenges to HSI:** Human factors and health and medical programmatic requirements are handled differently in NASA between directorates and centers from an organizational standpoint. These organizational differences may lead to disconnects in understanding, accepting, resourcing, and complying with human systems integration requirements. Organizations and communication chains currently in use have not changed in decades, while the ability to design, build, and operate ever more complex, human-rated systems continues to improve.

Recommendations

Cultural and practical bridges need to be built between the communities of practice responsible for the design, development, and operation of NASA systems. This must be done with a full awareness and appreciation of past evidence and experience. Cultural challenges have also been critical in international programs where medical systems, cultural norms, and constructs of peer-reviewed science have been vastly different. The efforts between NASA and its international partners, specifically the Soviets/Russians beginning in the early 1970s, have aptly demonstrated these challenges, and the engineers and life scientists moved forward with full knowledge of these differences and the sensitivities to those. Through the course of this manuscript, we have

identified potential misinterpretations and provided examples of improving communication and understanding between engineering and medical/life sciences communities. Definitive recommendations on accomplishing this are provided below:

1. Recognize the fact that deep cultural differences between communities of practice involved in NASA system development and operations exist. These cultural differences pose a risk to effective HSI.

2. Address cultural differences, primarily between engineering and medical/life sciences communities, early in the career paths of practitioners. Given the importance of human-rated and -operated systems, not just to NASA but across society, these differences should be formally addressed in the early training curricula of both engineering and medical/life sciences students in their respective professional schools.

3. Adopt a common lexicon and common means of communication, methods, and practices that are recognizable and understandable by all, as effective communication is imperative. In NASA, the Technical Authorities and the Mission Directorates should collaborate to produce training modules in NASA's learning management system—System for Administration, Training, and Educational Resources (SATERN)—to promote understanding of cultural differences and improve dynamics and the working relationship between engineering and medical/ life sciences communities. NASA should also establish a mandate for the Technical Authorities to emphasize effective HSI and to mediate and translate between the medical/life science and engineering communities. Medical/life sciences communities should leverage communication techniques used widely in systems engineering as much as possible. Medical/life sciences communities should utilize engineering risk analysis techniques when feasible. Engineering communities would be well served to consider the ethical approaches defined earlier in this manuscript when considering overall risk assessment and acceptance. The field of human factors is critically important as common ground for the intersection of all communities of practice in HSI and can serve as an effective agent and venue for change.

4. Create an imperative that all members of these diverse and relevant communities work together in a common platform to ensure the health and safety of the crewmember and the entire system that supports them from design and construction to operation. The diversity of thought/perspectives from each of the relevant communities is a necessity in order to have successful systems, and as such, those diverse

contributions must be actively engaged, encouraged and respected. Such a paradigm is critical in human space flight as it enters a new phase of deep space and planetary exploration.

5. Recognize that dynamic tension exists between Technical Authorities and program/project management. This tension is healthy in the vast majority of cases and should be lauded for its value in enhancing safety and the overall project/program success. Technical Authority should be embraced, protected, and preserved in NASA.

6. Engage the National Academies of Engineering, Science, and Medicine to study and comment on the imperative of cross-community collaboration and communication in HSI. This study could be facilitated by the Committee on Aerospace Medicine and Medicine of Extreme Environments and the Board on Human System Integration.

7. Study the disparate ways in which human factors and HSI are organized and addressed throughout NASA. Disconnects between requirements "ownership" and workforce management from center to center and directorate to directorate might contribute to the HSI challenges currently faced. A multidisciplinary team to fully study organizational challenges to effective HSI and to recommend changes to address those challenges should be considered.

8. Inclusion of all responsible and relevant communities of practice in all phases of the project/program, from design to operations, is absolutely necessary. Inclusion of communities late, almost as an afterthought, has demonstrably untoward and sometimes tragic effects.

9. The ethics-based decision-making framework that has been implemented for health and medical risks should also be considered for use in other risk acceptance paradigms. The same ethical principles and responsibilities could be applied to risk analysis, mitigation and acceptance in the safety and engineering realms as well. This would provide a broader context for risk decision-making and result in a stronger foundation to support the acceptance of higher risk levels, particularly in situations where mitigation strategies are inadequate or not available. Incorporation of a formal role for ethical considerations in engineering and safety risk analysis and decision-making could ultimately result in more comprehensive mission planning and management.

10. Finally, stress the importance of organizational leadership in achieving successful HSI. Ultimately, effective HSI is clearly a leadership responsibility. Communication and understanding between diverse communities of practice must be inculcated as an organizational core value, repeatedly emphasized by leadership as an imperative.

Conclusion

In the realm of human behavior, recognition and understanding that a problem exists is the first step in remediating that problem. In this manuscript, we have recognized that perennial problems have plagued HSI and continue to in the most current systems development efforts. We have posited reasons for these problems, rooted for the most part in deep cultural differences between the communities of practice responsible for human-rated systems design, development, and operations. We have described examples of cross-cultural collaboration and proposed positive steps that can be taken to address cultural differences with the long-term goal of enhancing HSI effectiveness. We must achieve optimal HSI in the development and operations of all NASA systems, from basic research to space exploration systems, for mission success. On the ground, we have the luxury of stopping a test, with impact to budget and schedule. In flight, whether atmospheric or in deep space, we will not have that luxury.

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Acronyms

ACGME   Accreditation Council for Graduate Medical Education
ATD   Anthropometric Test Device

CAIB   Columbia Accident Investigation Board
CAC   coronary arterial calcium
CHI   crew health index
CCP   Commercial Crew Program

DoD   Department of Defense
DRM   Design Reference Mission

EEGS   Emergency Egress Guidance System
EELS   Emergency Egress Lighting System
EMU   Extravehicular Mobility Unit
ETA   Engineering Technical Authority
EVA   Extravehicular Activity
EVAC   evacuation of a crewmember

FMEA   failure modes and effects analysis
FOD   foreign object debris
FTA   fault tree analysis

GAO   Government Accounting Office
GCR   Galactic Cosmic Rays
GRC   Glenn Research Center

HGAS   High Gain Antenna Subsystem
HMTA   Health and Medical Technical Authority
HQ   Headquarters
HRP   Human Research Program
HSF   Human Space Flight

HSI	Human Systems Integration
HSIR	Human Systems Integration Requirements
HSRB	Human System Risk Board
IARV	Injury Assessment Risk Value
IOM	Institute of Medicine
IMCL	IMM Medical Conditions List
IMM	Integrated Medical Model
ISS	International Space Station
JSC	Johnson Space Center
LCS	Littoral Combat Ship
LES	Launch and Entry Suit
LOCL	loss of crew life
LOE	level of evidence
MIB	Mishap Investigation Board
MIT	Mishap Investigation Team
M&M	Morbidity and Mortality
MPVC	Multi-Purpose Crew Vehicle
NASA	National Aeronautics and Space Administration
NESC	NASA Engineering and Safety Center
NMIS	NASA Mishap Investigation System
NPD	NASA Policy Directives
NPG	NASA Policy Guidelines
NPR	NASA Procedural Requirements
NTSB	National Transportation Safety Board
OBOGS	On Board Oxygen Generating System
OCHMO	Office of the Chief Health and Medical Officer
PMC	Program Management Council
PRA	probabilistic risk assessment
SATERN	System for Administration, Training, and Educational Resources for NASA
SDO	Solar Dynamic Observatory
SE	Systems Engineering

S&MATA Safety and Mission Assurance Technical Authority
SME   subject matter expert
SOAP   Subjective Objective Assessment Plan
SOP   standard operating procedure

TA   Technical Authority
TVac   thermal vacuum

UAS   Unmanned Aerial Systems
UNICOM Universal Communications

WFF   Wallops Flight Facility

XPRAT   Cross Program PRA team

Key Terms

aerospace engineering
aerospace medicine
anthropometric
astronaut

Challenger
cognitive diversity
Columbia
communication
complex systems
conflict resolution
crewmember

decision-making
domains

engineering
environment
ergonomics
ethics-based
ethical principles
ethical responsibilities
evidence
evidence-based
extravehicular activity

facility system safety
failure analysis

gender
governance

hazards of space flight human error
health
health and medical technical authority
high performance
human centered
human factors
human-machine interface
human-machine interdependence
human-machine strengths
human-machine challenges
human-machine error
human-machine diversity
human-rated
Human-Research Program
Human-system risk assessment
Human-Systems Integration
Human-systems interface
HSI

integration
in-flight
Integrated Medical Model
Institute of Medicine

Johnson Space Center

Kennedy Space Center

launch and entry suit
lifecycle costs
life sciences

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