A Framework for Multinational Medical Support for the International Space Station: A Model for Exploration

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INTRODUCTION: In the 1990s, Canada, member states of the European Space Agency, Japan, the Russian Federation, and the United States entered into an international agreement 'Concerning Cooperation on the Civil International Space Station'. Among the many unique infrastructure challenges, partners were to develop a comprehensive international medical system and related processes to enable crew medical certification and medical support for all phases of missions, in a framework to support a multilateral space program of unprecedented size, scope, and degree of integration. During the Shuttle/Mir Program, physicians and specialized experts from the United States and Russia studied prototype systems and developed and operated collaborative mechanisms. The 1998 NASA Memoranda of Understanding with each of the other four partners established the Multilateral Medial Policy Board, the Multilateral Space Medicine Board, and the Multilateral Medical Operations Panel as medical authority bodies to ensure International Space Station (ISS) crew health and performance. Since 1998, the medical system of the ISS Program has ensured health and excellent performance of the international crews—an essential prerequisite for the construction and operation of the ISS—and prevented mission-impacting medical events and adverse health outcomes. As the ISS is completing its second decade of crewed operation, it is prudent to appraise its established medical framework for its utility moving forward in new space exploration initiatives. Not only the ISS Program participants, but other nations and space agencies as well, concomitant with commercial endeavors in human spaceflight, can benefit from this evidence for future human exploration programs.

KEYWORDS: International Space Station, international medical system, exploration, multilateral, policy, spaceflight.

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Collaboration in human spaceflight among nations began in earnest in the 1960s. In early bilateral dialogue between U.S. President John F. Kennedy and USSR Premier Nikita Khrushchev, spacefaring nations discussed the possibilities of working together to achieve a common goal.[10–12] While not initially leading to joint missions, these discussions signaled the possibility for space program physicians, scientists, and engineers to collaborate. After the Moon landings, the U.S.-USSR Joint Working Group (JWG) on Space Biology and Medicine was created and held its first meeting in 1971.[5] With openness highly unusual for the times, both sides began sharing mission medical and research data; for example, medical summaries of Gemini 7 and Apollo 15 missions were presented by NASA experts while the Russian side shared knowledge on space station atmospheres.[16] The JWG also became a forum for coordination of experiments on the Bion and Cosmos satellites,[5] and ultimately served as the foundation for the Apollo-Soyuz Test Project (ASTP), which culminated in a July 15–24, 1975, joint flight (docking occurred on July 17, 1975).[12,13]

Once the political decision on a docking mission of the Apollo and Soyuz capsules was reached in 1972, the members

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of the JWG engaged with engineering specialists to solve the problem of differing atmospheric pressures and compositions in the two vehicles. The joint medical operations plan of ASTP was a major achievement; besides addressing the environment problems, it set the stage for a new level of international collaboration in space physiology and medicine.[6] Notwithstanding all the prior contacts between the U.S. and Soviet space medicine specialists, it was the ASTP that revealed and managed the many barriers to collaboration, such as differences in medical and engineering standards, culture, language, and operational philosophy.

Beginning in 1978, the Soviet Union provided citizens of other countries access to flights aboard Salyut 6, Salyut 7, and Mir space stations through its Interkosmos (Интеркосмос) program. In addition, during the period of 1983–2003, individuals from a variety of countries (Belgium, Canada, France, Germany, India, Israel, Italy, Japan, Spain, Russia, Saudi Arabia, Sweden, Switzerland, and Ukraine) flew on the U.S. Space Shuttles as spaceflight participants (payload specialists or mission specialists).

Shuttle/Mir—Phase 1 of the International Space Station Program

In 1984, President Ronald Reagan proposed that the United States partner with Western European countries, Japan, and Canada to build Space Station Freedom. During this same time period, the Mir Space Station Program continued to grow and involve international crewmembers. On June 17, 1992, U.S. President George H. W. Bush and the first President of the Russian Federation Boris Yeltsin concluded an agreement on 'Exploration and Use of Outer Space for Peaceful Purposes.' The William J. Clinton Administration invited Russia to join the development of an international space station; the invitation was accepted in 1993 and formalized in 1994 under the auspices of the 'U.S.-Russian Joint Commission on Economic and Technical Cooperation', co-chaired by U.S. Vice President Albert Gore and Prime Minister Viktor Chernomyrdin. The commission oversaw the establishment of the Shuttle/Mir program, known as Phase I, including the groundwork of its medical support.[9]

In the early 1990s, eight Russian cosmonauts participated in the Shuttle/Mir Program as Shuttle crewmembers, while seven U.S. astronauts completed long-duration tours on Mir (**Table I**). Each of these missions enriched the collective experience of the aerospace medicine community in the intricacies of international human spaceflight. Notably, Shuttle/Mir signified the progression from an intermittent host-visitor relationship toward a stable bilateral system of medical support, which was seen as the precursor of the International Space Station (ISS) multilateral medical organization.

Prior to commencement of Shuttle/Mir missions, medical experts from the United States and Russia, under the leadership of the JWG, worked together in the newly established Medical Operations Working Group to define the operational medical support system and prepare for crew exchanges in both Shuttle and Mir operations in Phase I.[8] The lessons learned from the interactions of U.S. and Russian specialists in nominal Phase 1 flights, and several serious off-nominal situations, were instrumental in the development of the medical and environmental requirements for ISS, which were officially approved in September 1998.[9]

Thus, Phase 1 medical operations served as the foundation for the development of the framework that the ISS uses today.[7] Following the Intergovernmental Agreement[15] among the partner states, the final memoranda of understanding (MOU) between NASA and the four cooperating agencies of the ISS Program (Canadian Space Agency, European Space Agency, the Science and Technology Agency of Japan, and the Russian Space Agency) were signed on January 29, 1998, to replace the three earlier MOUs from 1989,[14] i.e., before Russia's participation in the program was proposed and confirmed (1993).[4]

Article 11.4 of the new MOUs defined the framework for ISS multilateral medical operations. The medical leadership of all five partners was already proactively engaged in developing work on the ISS Medical Operations Requirements Document (MORD) and the common medical standards for selection of crewmembers for the ISS Program (**Fig. 1**).

Organizational Structure

The medical management structure of the ISS Program was created in accordance with Article 11.4 of the MOUs (**Fig. 2**), which provided the framework and the cardinal principles of multilateral authority and decision-making. Similar to other MOU clauses, Article 11.4 was neither intended nor written to address all aspects of the Multilateral Medical Policy Board (MMPB), the Multilateral Space Medicine Board (MSMB), or the Multilateral Medical Operations Panel (MMOP) function. Integration of Article 11.4 took place through programmatic documentation, such as the Station Program Implementation Plan (SPIP) and the charters of each medical board/panel. The principles of medical management in MOUs and SPIP were reflected in the 'ISS Medical Operations Requirements Document (ISS MORD)', which was generated by the MMOP. Specific roles and responsibilities, functionality, forums, and interfaces of the MMOP, the MSMB, and the MMPB were further discussed and coordinated using their charters as vehicles for negotiation among the five agencies and the ISS Program management.

Article 11.4 stipulated the development of medical standards and requirements as a function of the MMOP and specified an approval pathway through the MSMB. In addition to ISS medical operations design and implementation, the MMOP was further charged with ongoing functions to oversee joint medical operations and to maintain mission medical readiness assessment and reporting processes. In the nominal operational paradigm, the ISS Program defined a dual primary interface for the MMOP; medical policy matters would be communicated with the highest medical authority (the MMPB), while operational implementation and budgetary matters were to be approved by the highest-level operational authority [ISS Multilateral Mission Operations and Integration Board (MMIOCB)]. The latter reporting pathway enabled mission readiness and

Table I. Astronaut and Cosmonaut Participants of the Shuttle/Mir Program.

NAME	MISSION	DURATION	DATES
Sergei K. Krikalev (Russia)	STS-60 (no rendezvous with MIR)	8 d, 7 h	Feb. 3–11, 1994
Vladimir Titov (Russia)	STS-63 (rendezvous only)	8 d, 6 h	Feb. 3–11, 1995
Norman Thagard (USA)	↑Soyuz TM-21 / ↓STS-71 (Mir 18)	115 d, 8 h	March 14, 1995–July 7, 1995
Anatoly Solovyev (Russia)	STS-71	9 d, 19 h	June 27–July 7, 1995
Nikolai Budarin (Russia)	STS-71	9 d, 19 h	June 27–July 7, 1995
Gennadi Strekalov (Russia)	STS-71	9 d, 19 h	June 27–July 7, 1995
Vladimir N. Dezhurov (Russia)	STS-71	9 d, 19 h	June 27–July 7, 1995
Shannon Lucid (USA)	↑STS-76 / ↓STS-79 (Mir 21)	188 d, 4 h	March 22, 1996–Sept. 26, 1996
John Blaha (USA)	STS-79 / ↓STS-81 (Mir 22)	128 d, 6 h	Sept. 16, 1996–Jan. 22, 1997
Jerry Linenger (USA)	↑STS-81 / ↓STS-84 (Mir 22/23)	132 d, 4 h	Jan. 12, 1997–May 24, 1997
Yelena Kondakova (Russia)	STS-84	9 d, 4 h	May 15–24, 1997
C. Michael Foale (USA)	↑STS-84 / ↓STS-86 (Mir 23-24)	144 d, 13 h	May 15, 1997–Oct. 5, 1997
David Wolf (USA)	↑STS-86 / ↓STS-89 (Mir 24)	127 d, 19 h	Sept. 25, 1997–Jan. 31, 1998
Salizhan Sharipov (Russia)	STS-89	8 d, 19 h	Jan. 15–25, 1998
Andrew Thomas (USA)	↑STS-89 / ↓STS-91 (Mir 24-25)	140 d, 15 h	Jan. 22, 1998–June 12, 1998
Valery Ryumin (Russia)	STS-91	9 d, 19 h	June 2–12, 1998

STS = Space Transportation System; ↑ = launch; ↓ = return; d = days; h = hours.

mission status input, communication of operational concerns and requests, as well as cost, technical, and engineering decisions related to medical operations. In the final medical authority arrangement with the ISS Program, the MMOP was delegated control of the medical requirements and medical standards documentation, with concurrence of the MSMB and the MMPB for medical standards and with the MMIOCB approval of changes that entailed additional costs or affected nonmedical organizations or processes.

The MSMB functions as the medical board with final authority for crew medical certification. The MMPB serves for policy formulation and conflict resolution should the MSMB or the MMOP fail to reach consensus on matters within their respective responsibilities.

Governance

Article 11.4 of the MOUs delineates how the three entities (the MMPB, the MSMB, and the MMOP) are structured and where they interface with the ISS Program management. Each of these groups have established charters and structures that ensure their efficient operation. The MMPB and the MSMB have U.S. and Russian co-chairs. The MMOP chair rotates among the five partners on an annual basis, with the U.S. member otherwise serving as a co-chair to help coordinate functions and logistics. All members of the three multilateral bodies are physicians with significant experience in the discipline of space medicine (see **Fig. 3**).

The MMOP receives specialized expert input from its 12 chartered working groups across a range of disciplines and depends on their multilateral input for both standard-setting and ongoing management of medical operations. In addition, unique challenges have resulted in the creation of ad hoc "tiger teams" or permanent "sub-working groups" dedicated to specific areas of focus.

The MMOP also conducts a weekly virtual meeting as the ISS Space Medicine Operations Team to review all aspects of current medical operations, including ISS crewmember health status and concerns. As of February 2020, this forum had met 1000 times since the beginning of ISS habitation.

Multilateral documentation. As the Phase 1 Program was coming to an end and the ISS Program was ramping up, the framework laid out in Article 11.4 of the MOU began addressing significant issues related to multilateral foundations of crew selection, crew training, on-orbit medical operations, environmental monitoring capabilities, countermeasures, and extravehicular activities. Medical personnel, biomedical engineers, and life scientists were also participants in other system integration issues that were related to human health and performance.

In the early construction phase of the ISS, in parallel with the coordination of the MMPB, the MSMB, and the MMOP

Fig. 1. Medical representatives of the five ISS Agencies at the 3rd meeting of the ISS Multilateral Medical Operations Working Group [later renamed the Multilateral Medical Operations Panel (MMOP)], Houston, TX, USA, 1997. From left to right: Tadashi Murai, Michael Barratt (standing), Chiharu Sekiguchi, Ashot Sargsyan, Alexander Kulev, Charles Doarn, Alexander Kulev, James Collier, Valeri Morgun, Valeri Bogomolov, Gary Gray, Volker Damann, Roger Billica, and Yuri Kataev (courtesy of NASA).

11.4. NASA, ESA and the other partners will establish a Multilateral Medical Policy Board (MMPB) to provide coordination and oversight of crew health issues. NASA and ESA will each provide a single point of contact for medical support who will have full responsibility on behalf of its respective agency to resolve issues related to the development of a common system for medical support. The MMPB will be supported by a Multilateral Space Medicine Board (MSMB) and by a Multilateral Medical Operations Panel (MMOP), established by NASA and ESA with the other partners, which will be the primary working level groups for coordination of crew health matters including clinical care, medical standards, preventative medicine (including operational countermeasures) and environmental monitoring. The MMOP and the MSMB will operate on the principle of consensus. The MMOP will develop medical standards, certification criteria, pre-flight, in-flight, and post-flight medical care requirements, medical hardware responsibilities and operational procedures and recommend them to the MSMB for approval. The MSMB will present its decisions and findings to the MMPB and MCOP, as appropriate, for review and concurrence. NASA and ESA will be responsible for medical certification of their respective crew members in accordance with agreed standards, and will present the appropriate documentation to the MSMB for approval. The MSMB will have responsibility for final medical certification of crew and for oversight of the implementation of medical operations.

Fig 2. The text of Article 11.4 of the ISS Memorandum of Understanding (MOU) between NASA and ESA signed into force on January 29, 1998. There are three other MOUs, with the same contents, between NASA and three other partner agencies.

charters, two documents were developed to establish the high-level medical requirements of the program: ISS MORD and the three ISS Medical Evaluation Document (MED) volumes. The MMOP Working Groups were responsible for coordination of requirements in their respective areas of expertise, as well as for ongoing maintenance of those areas through recommendations to the MMOP.

The MORD was to define all aspects of medical operations in a high-level programmatic set of requirements, which would be adopted by the program as mandatory conditions for safe operation of a crewed station. Any requirements levied by the multilateral medical community, which the program would be unable to satisfy, were tracked as "unmet requirements", resulting in a waiver or awareness of added risk to health or performance. The MORD would also serve as a foundation for implementation documentation. As shown in **Table II**, ISS MORD continued to adapt to changing policies, new evidence, and programmatic revisions.

Despite the great difference in the size of the five partners' crew cohorts, all partners participated in the development of the second set of high-level medical requirements and medical standards, eventually called MED Volumes A, B, and C. These documents define crewmember testing routines for medical certification (part of Volume A) and in relation to flight (Volume B). Volume A also stipulates the process of medical certification, including the list of causes for rejection. Joint standards are essential for the operation of the certification process by the MSMB. All partners committed in a joint memorandum to full disclosure of medical information on each crewmember candidate and to decision-making by consensus. The MED Volume C is a set of relatively permissive selection standards developed for medical certification of individuals without operational responsibilities who would visit the ISS for a short period of time as "spaceflight participants" or "tourists".[2]

The framework also includes a wide variety of other documentation, all developed by multilateral medical leadership and subject matter experts. Table II lists the various types and levels of documentation that supports this framework.[15]

Challenges and Opportunities

As the ISS Program continues its service as a mature laboratory and a testbed for the future of human spaceflight, national and commercial space organizations continue to evolve and will likely build new partnerships to pursue even more ambitious goals, such as human missions to the Moon, Mars, and other destinations in the solar system.[3] A proven framework of the ISS collaboration represents a tremendous value to future partnerships. Any strong evidence from over three decades of the ISS collaboration should continue to be shared through scholarly forums for academic analysis to assure the best possible risk postures and health outcomes of future missions.

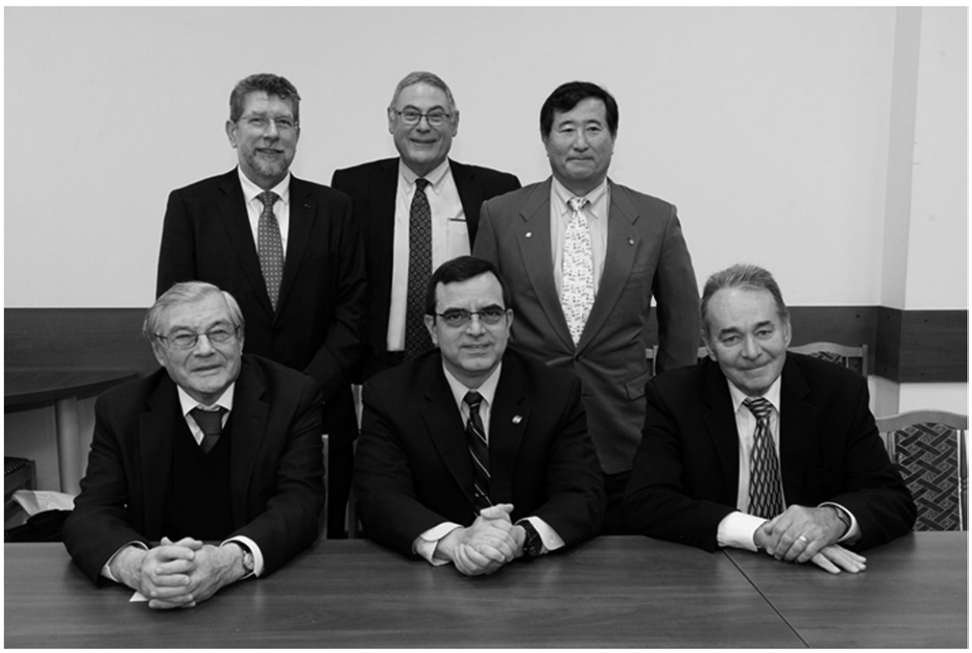

Fig 3. Multilateral Medical Policy Board (MMPB) Members in Moscow, Russia, in October 2018. Front row (L-R): Anatoly Grigoriev (Roscosmos), J. D. Polk (NASA), and Jean-Marc Comtois (CSA); back row (L-R): Guillaume Weerts (ESA), Charles Doarn (Executive Secretary, NASA), and Kazuhito Shimada (JAXA). (Courtesy of SC Roscosmos.)

Since the beginning of human spaceflight in the 1960s, the evidence base of space medicine has grown in parallel with the growth of medicine at large, in some areas positioning space medicine at the forefront of advanced technology utilization and medical innovation (e.g., telemedicine and ultrasonography of the eye). Another prominent success of space medicine is in its ability to create and operate a most sophisticated

Table II. Framework Documentation Development and Implementation Timeline.

DOCUMENTATION	TIME PERIOD	AUTHORITY	PROGRAM PHASE, NOTES
Intergovernmental Agreement	1993–1998	Nations	Shuttle / Mir - ISS
MOUs	1993–1998	Agencies	ISS
Charters (MMPB, MSMB, MMOP)	1998	Agencies and ISS Program	ISS
ISS MORD	Initial release: 1998	MMOP	ISS
MED Volume A	Initial release: 2005	MMOP	NASA document (AMERD) was used as an interim joint standard with agency-specific modifications
MED Volume B	Initial release: 2004	MMOP	
MED Volume C	Initial release: 2002	MMOP	ISS, specific to spaceflight participants
MMPB Policy Directives	2003, 2005, 2007, 2011	MMPB	ISS
ISS Generic Ground rules and Scheduling Constraints, medically relevant sections		MMOP	ISS
ISS Flight Rules, Aeromedical section	Updated as necessary	MMOP	ISS
MMPB Framework Document	Initial release: 2010	MMPB	ISS
ISS Joint Medical Operations Implementation Plan (JMOIP)	Initial release: 2015	MMOP	Includes Annexes: Flight Surgeon Training Document and Infectious Disease Prevention Document

MOU: Memorandum of Understanding; MMPB: Multilateral Medical Policy Board; MSMB: Multilateral Space Medicine Board; MMOP: Multilateral Medical Operations Panel; ISS: International Space Station; MORD: Medical Operations Requirements Document; MED: Medical Evaluation Document.
Med Volumes A, B, and C are updated as necessary to reflect growing and changing evidence in space medicine and terrestrial medicine at large.

international medical system, which has identified and tested solutions to numerous challenges (e.g., culture and medical practice, language, standardized protocols). It is widely believed by many mission planners and visionaries that a sustainable, long-term program of human space exploration should be international. With that presupposition, it will unquestionably mean the practice of space medicine in a functional multilateral medical system and the robust, time-tested medical organization of the ISS Program represents a validated precedent.

Characteristics of the ISS Multilateral Medical Policy

Pursuing a single goal to ensure the best possible health outcomes for the ISS crew, ISS medical policy foresees an 'integrated health support system operating on the best available evidence, with the best available resources, and to the highest ethical standards' as an essential system to the success of the ISS Program. Since the early 1990s, five international agencies, representing 26 nations, agreed to common standards and medical requirements that often differ from those used by each nation, individually. Principles that govern the selection and certification of crewmembers for flight, training, and certification of specialized aeromedical physicians (flight surgeons) to support ISS missions have been carefully developed and integrated across diverse medical cultures and national legislations.

The concept of consensus decision-making has served this program very successfully. The MMOP is the foundation for which this consensus is relegated. If the MMOP cannot come to a successful operational decision, the concern is escalated to the MMPB for resolution. In over 25 yr of ISS partnership, this process has rarely been invoked, demonstrating that the framework, established in the 1990s, has retained its effectiveness throughout decades of ISS operations. Also, over the course of 25 yr, policy statements promulgated by the MMPB in support of the MMOP's and the MSMB's functions have been exceptionally constructive in enabling and safeguarding a unique multilateral healthcare system.

As the ISS grew in size and complexity, the various specialized working groups, subgroups, and teams of the MMOP addressed a multitude of issues that were instrumental to construction and utilization of ISS. Some of these groups, highlighted below, continue to meet regularly while others interact less frequently based on need.

Working Group
- Biomedical Training
- Biomedical Operations
- Countermeasures
- Environmental Health
- Human Behavior and Performance
- Extravehicular Activity
- In-Flight Clinical Medicine
- Medical Informatics and Technology
- Medical Standards and Health Evaluation
- Nutrition
- Postflight and Rehabilitation
- Radiation Health

Subgroups
- Acoustics and Audiology
- Air Quality
- Fatigue Management
- Microbiology
- Spaceflight Associated Neuro-Ocular Syndrome
- Water Quality

Tiger Teams
- Crew Fatality
- Increment Duration

New 'tiger' teams are developed to address emerging operational concerns. Every group is staffed by at least one subject matter expert representing each International Partner.

A Model for Transition to New Initiatives in Exploration

It was the vision and leadership of a few individuals in the late 1960s and early 1970s that laid the foundation of the

international space medicine community through the JWG[6] and the ASTP.[1] The design of the joint ISS health system was heavily influenced by all preceding international activities that incrementally grew a body of enabling knowledge and operational solutions. As the ISS continues to benefit humanity in its 20th year of continuous human presence as of 2020, the United States and other ISS partner nations are rapidly forming plans for even more complex and daring missions. Many nations and commercial entities have expressed ambitions to join the community of human spaceflight and exploration. The drive for exploration, so natural for the human species, shows no signs of remitting. The experience of the joint ISS medical system will remain a powerful reference for constructive international collaboration in the post-ISS era of expansion of the human presence off the Earth.

The various multilateral groups, described above, worked hard to overcome the boundaries of time zones, language, culture, geopolitical interests, and geography. Through integrative and collaborative interactions, an international health system was developed to support all phases of human spaceflight on the ISS. The creation of authorities of medical policy (the MMPB), requirement setting and operational oversight (the MMOP), and certification (the MSMB) with consensus decision-making provided a single strong integrating mechanism. A collective trust among the five agencies had to be rapidly built, assured, and upheld for the long-term operation of the program. The MSMB, by virtue of its medical certification role, could only function on the basis of common criteria on the one hand, and full disclosure of medical information on the other. The potential collision of national medical standards and approaches at this level could not be prevented by full disclosure alone. Shared desire to achieve consensus through rigorous review of medical decisions played a hugely constructive role by upholding the quality of crewmember assessments and evidence-based considerations, thereby minimizing crewmember disqualifications due to the lack of consensus.

Overall, this tripartite medical management structure in a sterling manner has successfully executed its responsibilities over the course of the ISS Program and continues to do so. During that time, challenges and opportunities arose and were addressed. Beyond the life of the ISS, human spaceflight programs will include exploration initiatives and commercial spaceflight, which will heavily rely on the medical and administrative evidence of unprecedented value that the ISS Program created.

As nations and commercial providers ponder new programs for space travel, they would be at a great disadvantage if they did not consider the ISS framework that has been operational for several decades. New programs will bring new partners and new ideas and this framework provides an excellent platform with which all of us can continue to learn from and benefit from.

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