# SPACE MEDICINE AND THE LAW

*The beauty of the cosmos continually inspires wonder and curiosity. Throughout history, space has provided humanity with both practical benefits and fertile grounds for the imagination. Together with future generations, we will be the next explorers to unravel the mysteries of the universe [United Nations, 1999].*

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Space medicine involves understanding and dealing with physiological and psychological effects on human in space environment and to adopt the necessary counter-measures. Medically significant aspects of space travel include weightlessness, strong inertial forces during liftoff and re-entry, radiation exposure, absence of the day and night, and existence in a closed environment. Space medicine is concerned, for instance, with osteoporosis caused by weightlessness and the resultant increased risk of fracture.[1]

Space Medicine is a developing area of health care that has roots in aerospace medicine but that is focused on the health of individuals so that they can perform in, and return in good health from, increasingly distant extreme space environments, for example, from short-duration space flights, long-term space station flights, missions to the Moon, and in the next stages, exploration-class missions beyond Earth orbit, including missions involving planetary colonization ["Safe Passage".[2] Space medicine has at its core the purpose of supporting the mission of human flight into and exploration of space.[3]

In this paper, the terms space tourist, space passenger, private space explorer, and spaceflight participant will be used interchangeably, except where specifically denoted.

**Definition of Space Medicine in an Astrosociological Context**

Space medicine requires another complementary dimension. In the area of space medicine, then, a focus on biology and physiology alone misses the social dimension that includes ethics and social inequality. Space medicine represents one side of a single coin on which medical astrosociology exists on the other side. The two brought together create a complete perspective in space research, just as terrestrial medicine and medical sociology belong together on Earth... Medical astrosociology turns the attention of those interested in space medicine from a social-scientific perspective to a single new specialization.[4]

In 1948, nine years before Sputnik I, Col. Harry G. Armstrong, convened a panel to discuss "Aero medical Problems of Space Travel." The panel discussion included presentations by Hubertus Strughold and Heinz Haber, two of the German physicians, and commentary from six noted university and military

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scientists. At this panel, Strughold first coined the term "space medicine in 1948. Later, through the excellence of his work, Dr. Hubertus Strughold (1898-1986) is nicknamed as the "Father of Space Medicine."

He was a co-founder of the Space Medicine Branch of the Aerospace Medical Association in 1950. In 1963, the Space Medicine Branch initiated the "Hubertus Strughold Award," which is given each year for the greatest achievement in space medicine.[5]

Recently, physician/astronaut, Dr. Joe Ker win, a former executive at Wyle who flew aboard the 28-day Skylab 2 mission in 1973 is honored by the Aerospace Medical Association (AsMA) at its annual conference in Phoenix in May 2010 for his works advances in the understanding of human physiology during spaceflight and innovation in the practice of space medicine.[6]

**Aviation medicine**

It is the study of the biological and psychological effects of aviation. Medically significant aspects of aviation travel include exposure to changing temperatures, large inertial forces, oxygen deprivation, and air sickness, as well as pilot fatigue. Aviation medicine is concerned, for instance, with the spread of disease by air travel and the adverse effects of noise and air pollution.

**Aerospace medicine**

The fields of medicine concerned with the maintenance of health, safety, and performance of those in aviation and space travel. Aerospace medicine is the sum of aviation medicine and space medicine-health in flight both inside and outside the Earth's atmosphere. Aerospace medicine is a sub discipline of preventive and emergency medicine that ties together physics, life support, and medicine to protect aircrew and patients in the realm of aerospace.[7]

The ambient environment quickly becomes hostile to humans. From the earliest physiologic observations of balloonists in the 1700s to Paul Bert's altitude chamber experiments in 1878 to the latest 2008 reports from the US Air Force School of Aerospace Medicine, our understanding of aerospace medicine has advanced exponentially. The US led War in Iraq and recent hurricanes and earthquakes have necessitated rapid advances in the technology and strategies available to rapidly evacuate critically wounded soldiers and large numbers of non ambulatory patients.[8]

The Indian Society of Aerospace Medicine was founded in 1952 with a charter to (a) advance the science and art of Aviation and Space Medicine, (b) establish and maintain co-operation between medical and other sciences concerned with aero medical development and progress and (c) promote, protect and maintain safety in Aviation and Space ventures. Towards furthering this cause the Society promotes the specialty by organizing annual conferences, facilitating its members to interact with specialists across the world, publishing a biannual Indian Journal of Aerospace Medicine and sponsoring research work to foster the spirit of the subject.[9]

Astro-scientist Prof. K. Kasturirangan has called for introducing Space medicine as a subject in medical courses in view of the tremendous potential in the field, he stated "In a space environment, the human beings face micro-gravity condition, it makes the flow of body fluids such as blood different from what we are accustomed to on the surface of the earth. This in turn alters the quantity and distribution of body fluid, being free of the gravitational effect."[10]

To provide necessary support to the Human Space Programme (HSP) of ISRO, the Institute of Aerospace Medicine IAF Bangalore has defined the following areas of work.[11]

(a) Selection of Vehicle Crew and Training.

(b) Environment Control and Life Support System (ECLSS).

(c) Human Engineering Work Station Design for Crew Module.

(d) Isolation and Psychological Management.

(e) Human Factors considerations in Manned Space programme.

(f) Microgravity Research.

(g) Gravitational Stress Management in various Phases of Space Flight.

(h) Clinical Space Medical and Surgical Management.

(j) Radiation Protection.

(k) Toxicology in Space.

(l) Emergency Survival System Design.

(m) Space Station Life Support System.

(n) Extra Vehicular Activity (EVA) Design.

(o) Heat Stress Management.

(p) Operational Space Medicine.

(q) Scientific and Technical Manpower Management.

(r) Infrastructure Development related to aero medical Support.

**NASA and Aerospace Medicine**

The successful launch of Earth's first artificial satellite by the Soviet Union on October 4, 1957, was the initial step in a series of events that made the State of Texas the home of the United States manned space-exploration program, for a combined total presence in space of more than 70 years.[12] *Sputnik* I provided the impetus for President Dwight D. Eisenhower to propose and Congress to approve the National Aeronautics and Space Act, which was signed into law on July 29, 1958.After World War II, 130 German scientists and engineers, led by

Werner von Braun, were brought to the United States and stationed at Fort Bliss in El Paso, Texas, to continue their work on rockets.

**Aerospace Medicine and Manned Space flight**

Project Mercury provided confidence in the ability of the astronaut to perform satisfactorily in the weightless environment and in the capability of the spacecraft environmental-control system to support life in space. In 1963, at the height of Project Mercury, had grown to 2,500 civil-service employees, but only about 500 supported Project Mercury. The rest of the employees were involved in preparing for the Gemini and Apollo projects. Project Gemini included twelve manned space flights. The Gemini spacecraft, launched by a modified Titan missile, carried two astronauts. The two longer flights, *Gemini V* (eight days) and *Gemini VII* (almost fourteen days), included nine medical experiments designed to investigate the problems identified during the Mercury missions. These experiments provided an opportunity for the medical community outside NASA to participate in the space-flight experiment program. The biomedical results of Apollo were impressive. The Skylab missions, which occurred between May 1973 and February 1974, differed significantly from all previous manned missions. From its inception, Skylab was intended to be a science program. The final flight of an Apollo spacecraft took place on July 15, 1975. The Apollo-Soyuz Test Project was a nine-day international mission; the first shuttle orbital flight was launched on April 12, 1981. Commanded by John W. Young with pilot Robert L. Crippen, this mission was a flight test of the Space Shuttle *Columbia*. The shuttle program was an outstanding success. Its performance was even better than anticipated until January 27, 1986, when the shuttle *Challenger* exploded shortly after liftoff. One of the solid rocket boosters malfunctioned, and the resulting explosion killed the seven crew members. By late 1994 Spacelab had flown eight times, and each mission included biomedical investigations.[13]

**Space Medicine: Challenges and Future direction**

The expansion of human space flight to low earth orbit and beyond over the past forty years has provided a challenge to clinicians responsible for the health and safety of astronauts. Space medicine is currently entering an evolutionary phase of incorporating the understanding of the physiological changes associated with human space flight into the prevention, diagnosis and therapy of illness and injury in space.

The operational priority for the next decade will be to develop and utilize the research capabilities of the International Space Station to enable safe human space travel beyond low earth orbit. The next phase of exploration may involve humans returning to the moon for prolonged periods at lunar habitats, or could involve sending humans to Mars to search for evidence suggesting the existence of life elsewhere in our solar system. If the development of space technology follows the rapid development of aviation over the past century, as we enter this millennium the humans may very well become a space faring society.[14] The day will come when some human beings will spend all their time in space.

**Voluntary reporting systems of medical issues**

An overarching paradigm describing space medicine is to expose the normal physiology of a career astronaut/cosmonaut to microgravity and subsequently mitigate the changes which could jeopardize on-orbit health as well as re adaptations to Earth. Gregory Olson, the third spaceflight participant to International Space Station, was exceptionally forthcoming in allowing his complex medical case to be published in the medical literature. The article "Medical Qualification of a Commercial Spaceflight Participant: Not Your Average Astronaut" documented the efforts to take an initially medically disqualified individual and successfully fly him after appropriate intervention.[15]

Knowledge gained from this case and other future challenging cases will provide space medicine with an evidence-based approach to address medical standards and onboard medical care systems. A voluntary national reporting system could potentially be established to create a repository of knowledge on items such as types of medical conditions evaluated and approved /disapproved for flight, scope of diagnostic evaluations or treatments utilized to clear a given patient, medical or safety incidents arising during preflight training and all phases of flight. This system would help promote health and safety by increasing knowledge in space medicine about the physiological impacts of flight on a host of underlying pathologies and conditions. Participation by foreign companies in such a system would certainly add to this information, thus serving passengers and crew safety internationally.

NASA, wishing to broaden its knowledge of space medicine and promote safety, may be well suited to become a data management clearinghouse for such a reporting system.[16] The current NASA Longitudinal Study of Astronaut Health (LSAH) is an established database compiling and evaluating information on active and retired Astronauts across a spectrum of physiological/clinical parameters and mission profiles. Such a program can mitigate risk and decrease liability as both the medical community and business enterprises strive to maximize health and safety for the flying public.[17]

In 1999, the Aerospace Medical Association (AsMA) approved a resolution urging that appropriate agencies develop relevant U.S. Federal policies, procedures, guidelines, and regulations to guarantee the health and safety of human crewmembers and passengers involved in manned commercial space flights. On November 20, 2000, AsMA convened a task force to develop a position paper on "Medical Guidelines for Space Passengers". Two sets of guidelines were published in the "Aviation, Space and Environmental Medicine" journal in the October 2001 and November 2002 issues.[18]

On February 11, 2005, the FAA Office of Aerospace Medicine released a report on "Recommended Guidelines for Medical Screening of Commercial Space Passengers" during the 8th FAA Commercial Space Transportation Forecast Conference.[19] The International Space Station (ISS) medical program has been developed by the five partner space agencies in the U.S., Russia, Europe, Canada and Japan. Medical standards have been developed as one aspect of the medical program and one specific set of standards addresses paying passengers called Space Flight Participants (SFP). These SFP standards permit flights up to 30 days in length.

U.S. is the only country that has established licensing requirements for manned commercial space operations. The U.S. Commercial Space Launch Amendments Act of 2004 (H.R. 5382) defines a suborbital space passenger vehicle, clarified the process of licensing such vehicles and authorizes FAA to issue permits, and allowed paying passengers to fly into space at their own risk.. The Act necessitates the space passengers to be fully informed about all of potential risks of participating in space flights. Since the beginnings of manned space exploration, relatively healthy professional astronauts have been selected to participate in space flights, and, from a medical fitness point of view, they should not be considered a representative sample of the general population. However, even among these professional astronauts who have been subject to very thorough initial medical selection tests and to subsequent medical screening and monitoring evaluation procedures, some have experienced a variety of ground and in-flight medical events.

**Medical liability during in-flight medical event:**

The standard of medical care expected of doctor passenger on board aircraft is the same as those for doctors working in a hospital environment. The medical standard of care is a medical judgment as established by the Bolam test in the landmark case of *Bolam v. Friern Hospital Management Committee*[20] Per McNair said: "The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well-established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art." Under the Bolam test, a doctor is not negligent if he has conformed with responsible professional practices. He is judged by the standard of awareness and sophistication to be expected of a doctor in his type of practice. A doctor conforming to responsible professional practices would not be negligent simply because 'there is a body of opinion who would take a contrary view'. To determine whether a doctor is negligent, the court will rely on expert professional opinion. The standard of medical care is a medical judgment *Sidaway v. Bethlem Royal Hospital Governors*.[21] The Bolam test established that the standard of medical care was that of professional colleagues, which must accord with a 'responsible body of medical opinion'. The Court of Appeal has ruled that the Bolam test is supplemented by the House of Lords decision in *Bolitho v. City & Hackney Health Authority*[22] in that "even if the doctor's actions were supported by a body of medical opinion, the court would still examine the expert testimony to see if it was founded on a logical basis". Thus the Bolam test does not give immunity from judiciary inquiry over the medical process. To qualify as a 'responsible' body of opinion, such testimony must satisfy the threshold test of logic. This means that the experts must direct their minds to the comparative risks and benefits and have reached a 'defensible conclusion' on the matter.

**Duty of care owed by volunteer doctors**

The passenger doctor does not owe a duty to volunteer medical help unless there is a pre-existing doctor-patient relationship. This is the case in the United Kingdom, United States, Canada and Singapore. In Singapore, doctors are bound by the Singapore Physicians' Pledge (derived from the Hippocratic Oath) and biomedical ethics to render medical assistance when they are asked to help. (Section 45 (1) (d) of the Medical Registration Act on 'professional misconduct'). Other European countries do impose an obligation to render assistance. America has the 1988 Aviation Medical Assistance Act which gives limited "Good Samaritan" protection to any medically qualified passenger who provides medical assistance on board an aircraft during an in-flight medical emergency. The doctor must be a 'volunteer' giving care in good faith and receiving no monetary compensation. Gifts in the form of travel vouchers or seat upgrades are not compensation. Although this Act frees the passenger doctor from responsibility for assisting during an in-flight medical emergency it does not free him if he is guilty of gross negligence or willful misconduct. It is interesting to note that the Aviation Medical Assistance Act also relieves airline carriers from liabilities due to the performance of the air carrier in obtaining the assistance of a passenger-doctor in an in-flight medical emergency.[23]

**Ethical Viewpoints from a Medical Perspective**

Space medicine, and terrestrial preventive and occupational medicine, cover similar grounds. Medical decision-making involves achieving a balance between safety, well-being, career livelihood of individuals and attainment of mission success. Every aspect of space medicine practice is influenced by these variables, from the mission design, development and execution to the selection, training, monitoring and follow-up of the crew. Given the potential hazards offered by the space environment, every in-flight medical contingency cannot be predicted. However, generalized on-board protocols for anticipated medical scenarios can provide a framework for crew and ground personnel to minimize deliberation when making decisions that will impact the mission such as evacuation or mission abort.[24]

**Doctor's ethical duties and liabilities**

All physicians should understand basic air evacuation principles in case natural or manmade disasters warrant mass evacuation such as happened after the Chinese earthquake in 2008 and Hurricane Katrina in New Orleans in 2005.[25] In ideal situations, during organized large civilian or military airlift operations, physician responsibilities include the following:

- Aero medical screening: Define the patient classification as ambulatory, litter, monitored, intubated, or psychiatric. This triage effort also entails a decision about "precedence" (now, soon, or when space is available), and special medical requirements such as suction equipment or IV drips.
- Validation: Review by an aero medical specialist when possible. This would be a civilian or military flight surgeon. Consult can be telephonic, but during large-scale evacuations, these specially trained physicians usually are prepositioned at the aero medical staging site (outbound airfield).
- Medical preparation: "Packaging" the patient for the stressors of flight including, splints, antiemetic, and stocking of sufficient supplies of required medications and equipment.
- Clearance: Final patient review and acceptance by receiving facility.[26]

**The Clinical Care Capability Development program**

As part of the Space Medicine Program at the Johnson Space Center, the Clinical Care Capability Development Program (CCCDP) is an endeavor to develop guidelines and practices to provide medical care onboard space vehicles such as the International Space Station. Prior to accepting any technology or recommending any technique it must be analyzed from the Space Medicine perspective. Procedures or techniques must be reviewed to determine the specific limiting factors that may be encountered in the space environment. Volatile anesthetics or intravenous fluids could not be used in the standard fashion, which requires gravity. Given the prohibitive costs involved in testing any procedure in orbit, the KC-135 aircraft becomes an essential microgravity test-bed. This aircraft constitutes the NASA Reduced Gravity Research Platform, and allows investigators to simulate the weightlessness of space while remaining only a few miles off the earth's surface.[27]

**Medical liability issues and other legal aspects**

The thorough study of medico-legal aspects of commercial orbital space flights aims to fulfill four objectives:

1. Ensuring passenger / flight participant safety;
2. Advancement of the commercial space flight industry;
3. Development of the rule of law against medical requirements in a new field of space applications; and
4. Guaranteeing certainty in medical and legal issues for commercial space flight operators.

This requires a consideration of the following legal issues: (1) the applicable law; (2) jurisdiction, authorisation and licensing; (3) liability for medical risk exposure; and (4) informed consent.[28]

It is assumed that international space law and the various national space legislations apply.

Following the launch of the first satellite in 1957, the United Nations formed the Committee for Peaceful Uses of Outer Space (UNCOPUOS) in 1959. This committee set up five major international treaties.[29]

**Jurisdiction, Authorisation and Licensing of International Treaties**

***The rescue treaty (1968)***

This treaty presents a convention on astronaut rescue and return of objects launched into space.

***Convention on registration (1974)***

Under international space law, a space object is to be registered by the launching State" in accordance with Article II of the Registration Convention. The State of registry pursuant to Article VIII of the Outer Space Treaty "shall retain jurisdiction and control over such object, and over any personnel hereof, while in outer space", Subject to certain restrictions including the application of state's national laws.

***Space liability treaty (1971)***

The launching country would be absolutely liable to pay compensation for loss of life, injury, or damage to property resulting from objects launched into space by that country.

Article III of the 1972 Liability Convention makes a "launching State" liable for damage caused to persons on board a space object where the damage is due to its fault or the fault of persons for whom it is responsible. Article I(c) defines a "launching State" as a State which launches or procures the launch of a space object, or a State from whose territory or facility a space object is launched.

***Outer Space Treaty (1967)***

This treaty establishes that outer space is not subject to national appropriation and is to be used only for peaceful purposes. Article VI of the 1967 Outer Space Treaty makes States Parties "bear international responsibility" for activities in outer space, even where such activities are carried out by non-governmental entities. Such activities require "authorisation and continuing supervision" by the appropriate State. This obligation is generally fulfilled through a licensing process. It is significant, however, that these treaties do not require States to adopt safety and certification standards for crew, vehicles or passengers.

***The Moon treaty (1979)***

It deals with commercial exploitation of the Moon. In addition to the above treaties, governments have adopted non-binding conventions. They are referred to as resolutions and mainly concern international broadcasting from satellites, remote sensing, and the use of nuclear power in space.

A lack of safety regulations could result in international liability under the Liability Convention... Thus far, no rule of customary international law has been developed regarding passenger safety or medico-legal liability in relation to commercial orbital space flights due to a lack of clear practice and the belief that such practice is obligatory.[30] Minimum regulation and general compliance to minimum passenger safety standards appear to be sufficient.[31] There are conventions listing other transportation systems' liabilities that can be used as a framework in the event of passenger death or injury. The ''Convention for the Unification of Certain Rules Relating to International Carriage by Air'' (Warsaw Convention1929), Article 17 declares an airline liable, for damage sustained in the event of the death or wounding of a passenger or any other bodily injury suffered by a passenger. If the accident which caused the damage so sustained took place on board the aircraft or in the course of any of the operations of embarking or disembarking.[32] If there is a claim against an air-carrier, under which jurisdiction can the injured passenger or next-of-kin sue? Under article 28 of the Warsaw Convention 1929, the passenger can choose one of four jurisdictions to sue, namely:

— The place of incorporation of the carrier

— The place where the carrier has its principal place of business

— The place of destination

— The place where the carrier maintains an establishment through which the contract was made.

The main advantage of arbitration is the easy enforcement of foreign arbitral awards over foreign judgments due to the multilateral treaty—the 1958 New York Convention on the recognition and enforcement of foreign Arbitral Awards.

**Liability under Tort/Delict and Contract Law**

Passenger liability can be established by contract or delict/tort if the applicable national law so provides. With respect to tort/delicts, in many jurisdictions such claims are subject to the lex loci delicti rule, the law of the "place of the wrong" being applicable. Criteria proposed in the determination of the applicable law include contractual stipulation, law of the plaintiff or defendant, or law of the forum.

**Waivers of Liability**

To stimulate space tourism industry, the parties' freedom of contract is upheld to the greatest extent possible. In this context it is also important to note that, while space flight remains inherently risky, the informed space tourists are voluntarily putting themselves at such high risk. Therefore, contractual waivers of liability, including in case of death of a space flight participant, would be recommended.

**Insurance**

Other mechanism to reduce the risks of medico-legal liability is insurance in the form of passenger life and passenger liability insurance policies. Passenger liability insurance protects the operator against its legal liability to passengers. Insurers undertake to pay on behalf of the insured entity all sums which the insured shall become legally liable to pay as damages.

**Informed Consent**

Each space flight participant has to provide his/her written informed consent to participate in the space flight as well as written certification of compliance with the physical examination.[33]

**Conclusion**

*"The best way to predict the future is to invent it".*

**—Alan Kay**

Space medicine that originated from aerospace medicine in the 1940s is now rapidly developing to meet the requirements when common citizens as well as astronauts expand their habitats to space. In the interest of promoting space medicine and its applications for the benefits of humankind, on Earth and in space, we commit to providing an international, intercultural, and interdisciplinary approach to the dissemination of knowledge in aerospace medical sciences and to the development of state-of-the-art space medicine in support of future space exploration.

When we legally investigate the topic then we find that, there are primarily two very distinct parts of our juridical work. We have to study existing applicable law especially Space Law, and also what should be the future law. It is generally agreed within the scientific community that provision of appropriate medical facilities and administration of quality health care to astronauts are of great importance. However, for the more complex and remote missions envisaged for the future, issues of liability, responsibility and damage relating to medical practice may take on a greater significance and will need to be addressed and expanded in national sphere as well as International sphere. We are attempting to use an international laboratory, investing in tomorrow, in search of greater scientific knowledge which may contribute to maintaining the beautiful environment on Earth so that the next generation can live safely. It is our hope that the importance of manned space development will be fully understood by more and more people.

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