Federal Aviation Administration

Challenges in Medical Certification of Passengers in Commercial Space Flights

Presented at: *UNAM*

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Regulatory Oversight

At the present time, the U.S. is the only country that has established licensing requirements for manned commercial space operations

The U.S. Commercial Space Launch Amendments (CSLA) Act of 2004 (H.R. 5382)

Requires space passengers to be fully informed about all of the potential risks of participating in space flights allowing them to fly at their own risk

Commercial Space Launch Amendments Act of 2004

The CSLAA was signed into law on December 23, 2004 to promote the development of the commercial human space flight industry

- ✓ The public interest is served by creating a clear legal and regulatory regime for commercial human space flight
- ✓ Establishes "Experimental Permit"
- ✓ AST has sole authority over licensing of suborbital vehicles
- ✓ Allows "informed consent" of the customer to accept the risks of spaceflight

Commercial Space Launch Amendments Act of 2004

As long as there are no paying customers aboard, the licensing requirements are less stringent in order to facilitate the flight testing/evaluation of new space vehicle concepts.

There is no limit on the total number of experimental flights permitted under the new licensing requirements.

Requires passengers to be fully informed about all of the potential risks of participating in space flights allowing them to fly at their own risk.

What potential risks should be disclosed?

What is an appropriate/sufficient full-disclosure of potential risks that would:

- **Minimize liability for the operator?**
- **Not produce excessive fear among prospective space participants?**

14 CFR Part 460, Subpart B
Launch and Reentry
with a Space Flight Participant

§ 460.45 Operator informing space flight participant of risk.

(a) Before receiving compensation or making an agreement to fly a space flight participant, an operator must satisfy the requirements of this section. An operator must inform each space flight participant in writing about the risks of the launch and reentry, including the safety record of the launch or reentry vehicle type.

An operator must present this information in a manner that can be readily understood by a space flight participant with no specialized education or training, and must disclose in writing:

(1) For each mission, each known hazard and risk that could result in a serious injury, death, disability, or total or partial loss of physical and mental function.

(2) That there are hazards that are not known.

(3) That participation in space flight may result in death, serious injury, or total or partial loss of physical or mental function.

(b) An operator must inform each space flight participant that the U.S. Government has not certified the launch vehicle and any reentry vehicle as safe for carrying crew or space flight participants.

(c) An operator must inform each space flight participant of the safety record of all launch or reentry vehicles that have carried one or more persons on board, including both U.S. government and private sector vehicles.

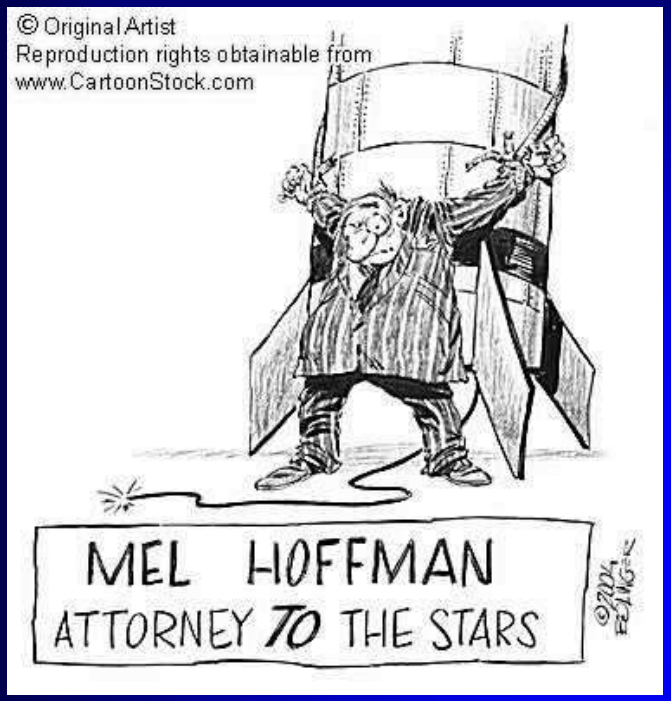
(d) An operator must describe the safety record of its vehicle to each space flight participant, including launch and reentry accidents and human space flight incidents that occurred during and after vehicle verification.

(e) An operator must inform a space flight participant that he or she may request additional information regarding any accidents and human space flight incidents reported.

(f) Before flight, an operator must provide each space flight participant an opportunity to ask questions orally to acquire a better understanding of the hazards and risks of the mission, and each space flight participant must then provide consent in writing to participate in a launch or reentry.

Why is Risk Disclosure Important?

Passenger Safety & Liability Issues



The problem is that we live in a litigious society where the safety of space passengers is a critical issue that the manned commercial space transportation industry must address proactively and comprehensively.

At the same time, the public has the right to take some personal risks!

"The greatest danger for most of us is not that our aim is too high and we miss it, but that it is too low and we reach it"

Michelangelo

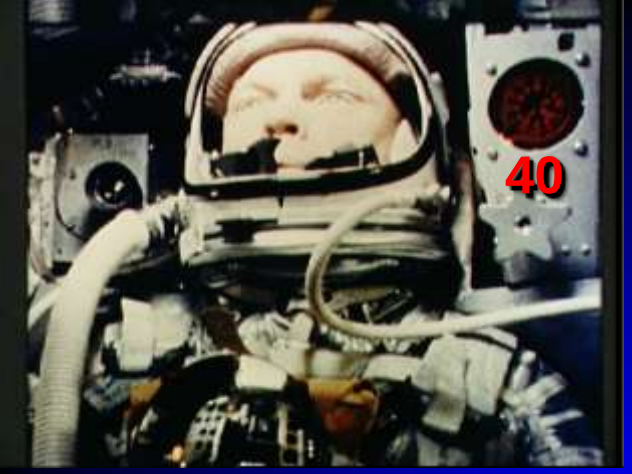
Always be prepared to deal with risks in disguise!

Do we know all the Medical Risks of Flying in Space?

NO!

We have very limited medical experience and knowledge on individuals with significant medical problems who have flown in space

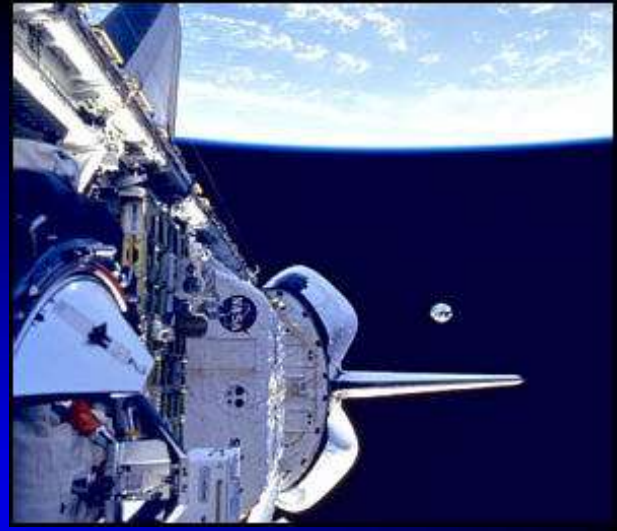
Most of the medical and physiological data collected to date are based on the effects of space flight on generally normal and healthy individuals (career astronauts and cosmonauts)



Until now most people who have flown in space are healthy career astronauts aged 35 to 50 years old (only exception is John Glenn)

Due to medical privacy regulations and career considerations individual medical data from career astronauts is not available for study by the scientific community

What Medical Data is Available to the Public?



U.S. Government Space Program Experience with Medical Pathology

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Ground Medical Events Among U.S. Astronauts

MEDICAL EVENT	FREQUENCY
Allergic reaction (severe)	1
Choledocholithiasis	3
Retinal detachment	2
Pancreatitis	2
Appendicitis	2
Diverticulitis	1
Ventricular tachycardia	1
Atrial fibrillation	1
Coronary artery disease	1
Hemorrhagic cyst	1
Abdominal pain	1
Duodenal ulcer	1

SOURCE: Jon Clark, MD, Space Medicine Liaison, National Space Biomedical Research Institute, Baylor College of Medicine, Personal Communication, 2007

Inguinal hernia	4
Ureteral calculus	3
Pneumonia	2
Sudden hearing loss	2
Cervical disk herniation with impingement on spinal cord	1
Corneal ulcer	1
Malignant melanoma	1
Severe epistaxis	1
Right ovarian cyst	1
Olecranon bursitis r/o septic joint	1
Clostridium difficile infection	1
Gastroenteritis/colitis	1
Dysmenorrhea	1

SOURCE: Jon Clark, MD, Space Medicine Liaison, National Space Biomedical Research Institute, Baylor College of Medicine, Personal Communication, 2007

Short-Duration Orbital Flights

Inflight Medical Events Among U.S. Astronauts

106 Space Shuttle Missions (Apr 1981 – Dec 2001)
607 Astronauts (521 men and 86 women)
5,496 Flight Days

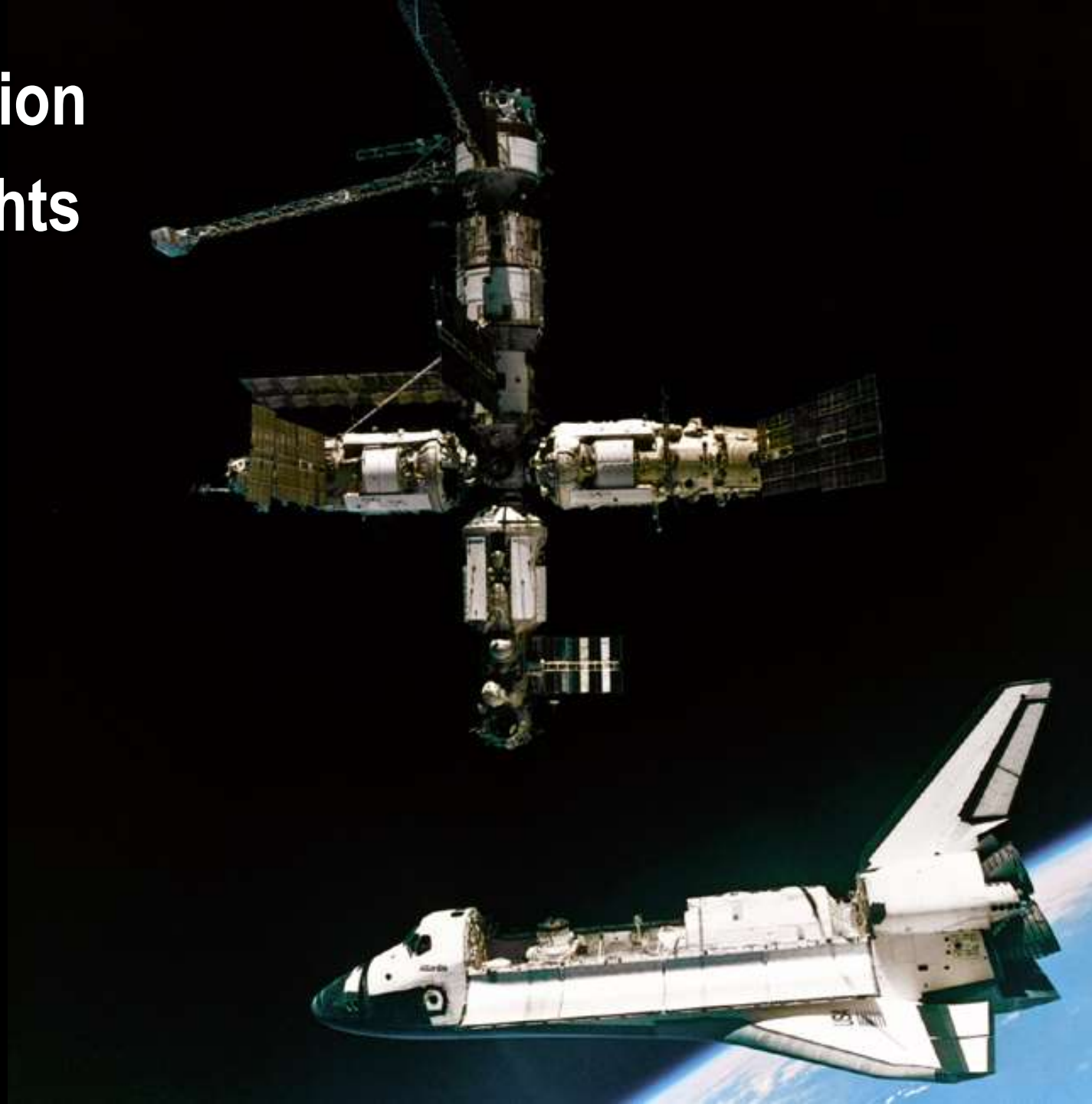
- *98.1% of men and 94.2% of women reported 2,207 medical events or symptoms during flight:*
  - Space adaptation syndrome (39.6%)
  - Nervous system and sensory organs (16.7%)
  - Digestive system (9.2%)
  - Injuries and trauma (8.8%)
  - Musculoskeletal system and connective tissues (8.2%)

- Skin and subcutaneous tissue (8%)
- Respiratory system (4.5%)
- Behavioral signs and symptoms (1.8%)
- Infectious diseases (1.3%)
- Genitorurinary system (1.5%)
- Circulatory system (0.3%)
- Endocrine, nutritional, metabolic & immunity disorders (0.1%)

194 events due to injury (including 14 fatalities)

SOURCE: Jon Clark, MD, Space Medicine Liaison, National Space Biomedical Research Institute, Baylor College of Medicine, Personal Communication, 2007

Long-Duration Orbital Flights



Inflight Medical Events Among U.S. Astronauts during the NASA/MIR Program (Mar 95 – Jun 98)

MEDICAL EVENT	FREQUENCY
Musculoskeletal	7
Skin	6
Nasal congestion, irritation	4
Bruise	2
Eyes	2
Gastrointestinal	2
Hemorrhoids	1
Psychiatric	2
Headaches	1
Sleep disorders	1

Inflight Medical Events Among Cosmonauts during the MIR Program (Feb 87 – Feb 96)

MEDICAL EVENT	FREQUENCY
Arrhythmia/conduction disorder	128
Superficial Injury	36
Musculoskeletal	29
Headache	24
Sleeplessness	19
Tiredness	14
Contact dermatitis	7

SOURCE: Jon Clark, MD, Space Medicine Liaison, National Space Biomedical Research Institute, Baylor College of Medicine, Personal Communication, 2007

Conjunctivitis	6
Laryngitis	6
Asthenia	5
Erythema of face, hands	4
Acute respiratory infection	3
Surface burn, hands	3
Glossitis	3
Dry nose	2
Heartbrun /gas	2
Foreign body in eye	2
Dry skin	2
Hematoma	1
Constipation	1
Eye contusion	1
Dental caries	1
Wax in ear	1



Medical Findings Among Commercial Orbital Space Flight Participants



Dr. Gregory Olsen

Dr. Gregory Olsen

- 57 year-old man with a history of pneumothorax, moderately severe emphysema, bilateral parenchymal bullae, pulmonary and mediastinal masses, and ventricular and atrial ectopy

- Received preventive treatment of these conditions, including surgery before being cleared to fly in space

- Completed medical evaluation in analog environments (altitude chamber, high altitude mixed-gas simulation, zero-G flight, and high-G centrifuge)

Jennings RT et al. "Medical Qualification of a Commercial Spaceflight Participant: Not Your Average Astronaut." Aviat Space & Environ Med Journal, Volume 77, No. 5, May 2006. (Dr. Olsen released his medical data)

Dr. Gregory Olsen

- Had no difficulties during the training and performed well during space flight
- Post-flight medical testing showed that he was in excellent condition and unchanged medically by the flight

Jennings RT et al. "Medical Qualification of a Commercial Spaceflight Participant: Not Your Average Astronaut." Aviat Space & Environ Med Journal, Volume 77, No. 5, May 2006. (Dr. Olsen released his medical data)

What is the impact of Dr. Olsen's decision to openly share his medical case?

- Provides the space medicine community with an opportunity to gain critical experience with non-career astronauts who have certain abnormalities to demonstrate that they could fly safely

- Enables the revision of medical screening criteria used by operators to accommodate individuals with certain abnormalities, optimize their pre-flight treatment and observe their performance during space flight

- Provides an opportunity for controlled study of adverse medical conditions in analog and space flight environments

- Provides medical knowledge that will prove extremely valuable for future human space exploration
- Benefits other individuals who may have similar medical conditions and wish to fly in space
- Demonstrates that space flight participants and their physicians can evaluate and accept some medical risks for performance testing in hazardous environments, pre-flight training, and space flight

Medical Screening Guidance for Commercial Space Flights

What is the minimum "Right Stuff" for passengers in commercial space flights?

Main Risk Factors Relevant to the Development of Guidelines for Medical Screening of Space Flight Participants

- Exposure to acceleration/deceleration
- Exposure to decreased barometric pressure
- Exposure to microgravity
- Exposure to radiation (solar and cosmic)

Orbital Space Flight Participants

Medical Guidelines for Space Passengers. Aerospace Medical Association (AsMA) Task Force on Space Travel. Aviation, Space & Environmental Medicine Journal, 72:948-950, 2001

Medical Safety and Liability Issues for Short-Duration Commercial Orbital Space Flights. Study Group 2.6, Commission 2 (Life Sciences), International Academy of Astronautics, 2009

Sub-Orbital Space Flight Participants

Medical Guidelines for Space Passengers -II. AsMA Task Force on Space Travel. Aviation Space & Environmental Medicine Journal, 73:1132-1134, 2002.

Guidance for Medical Screening of Commercial Aerospace Passengers. Federal Aviation Administration, Office of Aerospace Medicine, Washington, D.C. 2006. Technical Report No. DOT-FAA-AM-06-1

Sub-Orbital Crew Members

Medical Certification for Pilots of Commercial Suborbital Space Flights. AsMA Ad Hoc Committee. Aviat Space Environ Med 80: 824-826. 2009

Suborbital Commercial Space Flight Crewmember Medical Issues. Special Report. AsMA Space Flight Working Group. 2010

International Association for the Advancement of Space Safety (IAASS)

Suborbital Space Safety Technical Committee

Established three Suborbital Safety Working Groups: Regulatory, Technical and Operations

The Operations Working Group produced a report on recommended best practices on Flight Crew and Spaceflight Participant Medical and Training Requirements - 2013

IAA Study Group 2.6

"Medical Safety Considerations for Passengers on Short-Duration Commercial Orbital Space Flights"

The final report contains a list of medical conditions that could be adversely impacted by exposure to the operational and environmental risk factors in orbital space flights

FAA CST COE

Flight Crew Medical Standards

&

Spaceflight Participant Medical Acceptance Guidelines

Multiple organizations and interest groups have published medical recommendations for commercial spaceflight

There had not been a consolidation of these recommendations, guidelines, or standards into a cohesive document that could be operationally employed by commercial spaceflight operators, passengers and the FAA

NASA

SPACE TRANSPORTATION ASSOCIATION

FEDERAL AVIATION ADMINISTRATION

SPACE MEDICINE BRANCH · AEROSPACE MEDICAL ASSOCIATION

AEROSPACE MEDICAL ASSOCIATION

1. Spaceflight Participant Medical Acceptance Guidelines - Suborbital

2. Spaceflight Participant Medical Acceptance Guidelines - Orbital

3. Standards for Medical Certification of Pilots -Suborbital

4. Standards for Medical Certification of Pilots -Orbital

Final Report

www.coe-cst.org/publications.html

Medical Conditions that may Contraindicate Passenger Participation in Suborbital or Orbital Space Flights

Any deformities (congenital or acquired), diseases, illnesses, injuries, infections, tumors, treatments (pharmacological, surgical, prosthetic, or other), or other physiological or pathological conditions that may:

1) Result in an in-flight death
2) Result in an in-flight medical emergency
3) Interfere with the proper use (don and doff) and operation of personal protective equipment
4) Interfere with in-flight emergency procedures or emergency evacuation
5) Compromise the health and safety of the passenger or other space vehicle occupants, and/or the safety of the flight

Other Considerations

- Some medical conditions may be cleared for space flight following special medical assessments in simulated spaceflight environments including the use of a zero-G aircraft, a high performance aircraft, a hypobaric (altitude) chamber, or a human centrifuge

- Using a flexible approach that applies aerospace medicine knowledge and experience-based medical risk analysis, it may be possible to permit special medical accommodations for prospective participants who have certain pathologies (including disabilities)


NASA


AFRL CENTRIFUGE

Example

- Professor Stephen Hawking suffers advanced amyotrophic lateral sclerosis with significant mobility impairment and he was able to safely participate in a zero-G flight

- He was accompanied by a medical team (including an aerospace medicine specialist) who were involved in providing inflight medical support as needed

The aeromedical preparation for this very unique flight included:

1) A training flight carrying a healthy volunteer on the day before Professor Hawking's flight

2) The use of non-invasive biomedical monitoring equipment for blood pressure, heart rate, electrocardiography, respiratory rate, oxygen saturation and carbon dioxide saturation

3) A practical simulation of possible inflight medical emergencies


ZERO-G


www.goZeroG.com


Zero
the eightless experience

This zero-G flight demonstrated that it is feasible to allow selected individuals with severe disabilities (or other pathologies) to participate in short-duration space flights, but this may require:

1) A comprehensive preflight aeromedical preparation

2) Appropriate in-flight biomedical monitoring (including medical equipment and supplies)

3) It may even require a special flight dedicated to carry such an individual with real-time support provided by a medical team to ensure his/her health and safety

Medicine is a Science and an Art

The Key for CST HSF is the Medical Waiver Process

Other Considerations

- It is recommended to implement non-invasive biomedical monitoring of spaceflight participants prior to launch, during the entire flight, and in the immediate post-landing period

- The basic physiological parameters to be monitored include body temperature, heart rate, ambulatory electrocardiography, blood pressure, respiratory rate, transcutaneous arterial oxygen saturation (PSaO2) and carbon dioxide partial pressure (PaCO2)

- Such a monitoring system should be fully portable, light and compact, self-powered, built-in automated data collection and storage capability, non-invasive and minimally intrusive on the wearer

- Commercial space flights will create the opportunity for non-career astronauts with certain medical conditions to fly in space

- Medical information collected from space flight participants (specially those with medical waivers) will be extremely important to establish prospective medical databases by the operators

- Medical databases may include the results of the initial and pre-flight medical evaluations, the results of any inflight biomedical monitoring, as well as any post-flight medical findings

- All medical information collected and archived in databases should be protected to ensure the individual medical-legal privacy rights of space flight participants

- Post-flight medical debriefs are highly recommended to collect critical medical data and to resolve and/or follow up any health issues resulting from space flight

- A practical tool to facilitate and standardize these post-flight medical debriefs would be a questionnaire

Operator-owned medical databases will be of critical importance (medical & legal) to the success of the manned commercial space transportation industry, and, more importantly, to the health and safety of subsequent space flight participants

Other Guidance

- No conclusive data exist concerning the potential adverse physiologic and pathologic effects of space flight on infants or young children
- Operators may wish to establish a minimum age for passengers participating in space flights

Pregnancy Issues

- Because of the potential hazards of space flight (including exposure to solar and cosmic galactic radiation, acceleration, and microgravity), it is highly recommended that a female of child-bearing age be offered a pregnancy test

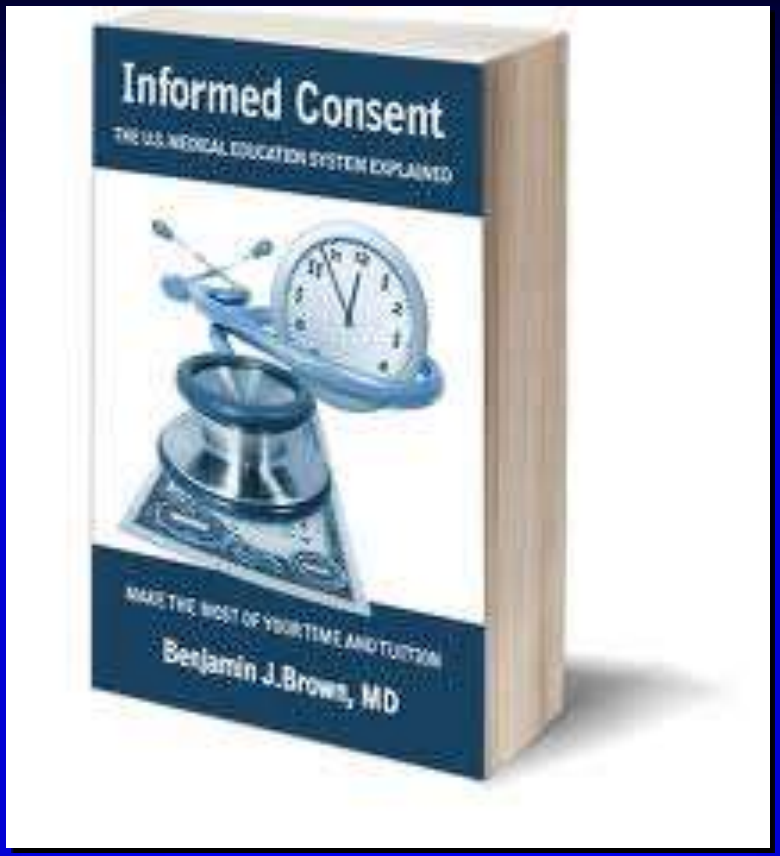
- Operators may wish to consider excluding pregnant women from participating in space flights, until more medical information becomes available to assess the actual risks of space flight for pregnant women and their unborn children

Controversial Consideration

- There may be some individuals suffering terminal medical conditions who may wish to participate in a space flight before they pass away
- Operators will have to decide whether or not such individuals will be allowed to participate in a space flight
- This will be a very difficult decision to make due to a number of significant ethical and legal implications

Operational Safety & Liability Issues

The reality is that we live in a litigious society



Medical Informed Consent

The Good, the Bad and the Ugly

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Medical Malpractice Insurance Issues for Commercial Space Company Physicians and/or Aviation Medical Examiners

Emergency Medical Readiness at Spaceports

ICAO Standards & Recommended Practices for Medical Facilities at International Airports

While provisions on medical facilities, ambulances and hospitals are mentioned in the ICAO Annexes and other pertinent materials, the decision on what to provide is left to the local authorities

Airport Disaster Drills

14 CFR PART 420
LICENSE TO OPERATE A LAUNCH SITE

420.53 Control of public access

(b) A licensee shall notify anyone entering the launch site of safety rules and emergency and evacuation procedures prior to that person's entry unless that person has received a briefing on those rules and procedures within the previous year

(c) A licensee shall employ warning signals or alarms to notify any persons at the launch site of any emergency

Other Practical Considerations

Other FAA CST COE Medical R&D Tasks

- Wearable Biomedical Monitoring Equipment for Space Flight Participants
- Medical & Physiological Database System for Commercial Space Flight
- Human System Risk Management Approach to Commercial Suborbital and Short Duration Orbital Flights
- Development of a Minor Injury Severity Scale (MISS) for Orbital Human Spaceflight
- Radiation and EMI Effects on Implantable Medical Devices

New Potential COE R&D Issues

Evaluate effects of exposure to repeated complex acceleration profiles (including +Gz and +Gx exposures) and their impact on performance and fatigue during repetitive simulated flights

Evaluate the methods, procedures, and technologies available for the protection of crew-occupied space in commercial spaceflight vehicles including a review of methods for the de-lethalization of the cabin environment, space vehicle crashworthiness, individual restraint systems, emergency evacuation systems, survival equipment, and related objectives

Evaluate the need for safety-related technical training standards for space vehicle crews and spaceflight participants

New Potential COE R&D Issues

Should a preflight quarantine/social isolation period be recommended to prevent the occurrence of acute infectious diseases during orbital flight?

Should there be medical criteria for early termination of an orbital flight due to unexpected illnesses or medical emergencies?

What types of medical conditions could result in an early termination of an orbital flight?

What type of emergency medical kits should be recommended to be carried on-board orbital commercial space vehicles (first aid, basic life support, advanced life support)?

What should be the minimum medical equipment and supplies included in an emergency medical kit for orbital inflight use?

Evaluate effects of exposure to repeated complex acceleration profiles (including +Gz and +Gx exposures) and their impact on performance and fatigue during repetitive simulated flights

New Issues

Should somebody (crew or passengers) be trained to use inflight medical kits and provide inflight medical care if needed? What should be the minimum knowledge and skills included in an inflight medical care training program?

How to formulate a practical definition of a medical hazard or operational risk that could result in a serious injury, death, disability, or total or partial loss of physical or mental function?